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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORPORATION, and HOLOGIC L.P.,

Plaintiffs,

vs.

SENORX, INC.,

Defendant.

AND RELATED COUNTERCLAIMS.

Case No. C08 00133 RMW (RS)

DECLARATION OF HENRY C. SU IN SUPPORT OF PLAINTIFFS' OPPOSITION TO SENORX, INC.'S MOTION FOR PARTIAL SUMMARY JUDGMENT OF NON-INFRINGEMENT ('813 PATENT, CLAIMS 11 & 12; '204 PATENT, CLAIMS 4 & 17; AND '142 PATENT, CLAIM 6)

Date: June 25, 2008
Time: 2:00 p.m.
Ctrm: 6, 4th Floor
Judge: Hon. Ronald M. Whyte

I, Henry C. Su, declare that I am a partner at the law firm Howrey LLP and a member of the bar of this Court, and I serve as outside counsel for Plaintiffs Hologic, Inc., Cytyc Corporation and Hologic LP ("Hologic"). The following declaration is based on my personal knowledge, and if called to testify, I could and would competently testify as to the matters set forth below.

1. Attached hereto as Exhibit A is a true and correct copy of excerpts from SenoRx's April 20, 2007 510(k) Notification regarding the SenoRad Multi-Lumen Balloon Source Applicator for Brachytherapy, produced by SenoRx with Bates numbers SRX-HOL00000413-495 (only relevant pages attached), marked *Confidential – Outside Counsel Only*, and filed under seal.

2. Attached hereto as Exhibit B is a true and correct copy of the Court's April 27, 2007 Claim Construction Order in *Xoft, Inc. v. Cytyc Corporation, et al.*, Case No. C-01-05312 RMW.

3. Attached hereto as Exhibit C is a true and correct copy of the Contura Multi-Lumen Balloon Source Applicator for Brachytherapy's Instructions for Use, produced by SenoRx with Bates numbers SRX-HOL00002232-3.

4. Attached hereto as Exhibit D is a true and correct copy of SenoRx slides pertaining to the accused device, produced by SenoRx with Bates number SRX-HOL00006665, marked *Confidential – Outside Counsel Only*, and filed under seal.

5. Attached hereto as Exhibit E is a true and correct copy of a document entitled "Contura - Frequently Asked Questions," produced by SenoRx with Bates numbers SRX-HOL00006684-86, marked *Confidential – Outside Counsel Only*, and filed under seal.

6. Attached hereto as Exhibit F is a true and correct copy of a SenoRx slide pertaining to the accused device, produced by SenoRx with Bates number SRX-HOL00001685, marked *Confidential – Outside Counsel Only*, and filed under seal.

7. Attached hereto as Exhibit G is a true and correct copy of excerpts from the April 4, 2008 deposition of Douglas W. Arthur, M.D., designated *Highly Confidential*, and filed under seal.

8. Attached hereto as Exhibit H is a true and correct copy of excerpts from the April 2, 2008 deposition of Philip Z. Israel, M.D., filed under seal.

9. Attached hereto as Exhibit I is a true and correct copy of excerpts from the April 2, 2008 deposition of William F. Gearhart, designated *Confidential*, and filed under seal.

10. Attached hereto as Exhibit J is a true and correct copy of a document entitled: "Contura - Frequently Asked Questions," produced by SenoRx with Bates numbers SRX-HOL00006598-6601, marked *Confidential – Outside Counsel Only*, and filed under seal.

11. Attached hereto as Exhibit K is a true and correct copy of SenoRx slides pertaining to the accused device, produced by SenoRx with Bates number SRX-HOL00006492, marked *Confidential – Outside Counsel Only*, and filed under seal.

12. Attached hereto as Exhibit L is a true and correct copy of SenoRx slides pertaining to the accused device, produced by SenoRx with Bates number SRX-HOL00006493, marked *Confidential – Outside Counsel Only*, and filed under seal.

13. Attached hereto as Exhibit M is a true and correct copy of SenoRx slides pertaining to billing and payment information for the accused product, produced by SenoRx with Bates numbers SRX-HOL00006624-6631 (only relevant pages attached), marked *Confidential – Outside Counsel Only*, and filed under seal.

15. Attached hereto as Exhibit N is a true and correct copy of excerpts from the May 20, 2008 deposition of James B. Stubbs, Ph. D., marked *Confidential – Outside Counsel Only*, and filed under seal.

16. Attached hereto as Exhibit O is a true and correct copy of a document entitled "510(k) Summary," dated May 18, 2007, produced by SenoRx with Bates numbers SRX-HOL00006605-6, marked *Confidential – Outside Counsel Only*, and filed under seal.

17. Attached hereto as Exhibit P is a true and correct copy of an excerpt from SenoRx's Contura MLB Source Applicator for Brachytherapy – Special 510(k), entitled "Device Description," produced by SenoRx with Bates numbers SRX-HOL00005563-65, marked *Confidential – Outside Counsel Only*, and filed under seal.

18. Attached hereto as Exhibit Q is a true and correct copy of SenoRx CTO Paul Lubock's November 6, 2002 patent application entitled "Vacuum Device and Method for Treating Tissue Adjacent a Body Cavity."

19. Attached hereto as Exhibit R is a true and correct copy of a July 22, 2004 Information Disclosure Statement submitted in support of SenoRx CTO Paul Lubock's patent application.

20. Attached hereto as Exhibit S is a true and correct copy of a Contura MLB Brachytherapy Applicator Clinical Data Report, produced by SenoRx with Bates numbers SRX-HOL00005395-5405, marked *Confidential – Outside Counsel Only*, and filed under seal.

21. Attached hereto as Exhibit T is a true and correct copy of a document entitled "Multi-Lumen Radiation Balloon (MLB) Background Information, produced by SenoRx with Bates numbers SRX-HOL00001535-37, marked *Confidential – Outside Counsel Only*, and filed under seal.

I declare under penalty of perjury that the foregoing is true and correct.

Dated: HOWREY LLP

By: /s/
Henry C. Su

HOWREY LLP
Attorneys for Plaintiffs
Hologic, Inc., Cytyc Corporation,
and Hologic L.P.

Exhibit B

E-FILED on 4/27/07

IN THE UNITED STATES DISTRICT COURT

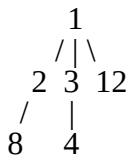
FOR THE NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

XOFT, INC., Plaintiff, v. CYTYC CORPORATION; and PROXIMA THERAPEUTICS, INC., Defendants.	No. C-05-05312 RMW CLAIM CONSTRUCTION ORDER **[Re Docket Nos. 48, 50, 53]**

Xoft, Inc. sued Cytyc Corporation and one of its subsidiaries, Cytyc Surgical Products II, Inc., (collectively "Cytyc") for a declaratory judgment of non-infringement and invalidity of U.S. Patent Nos. 5,913,813 and 6,413,204. Cytyc responded by filing counterclaims for infringement of the same patents and currently asserts that Xoft infringes six claims of the '813 patent[1] and twenty

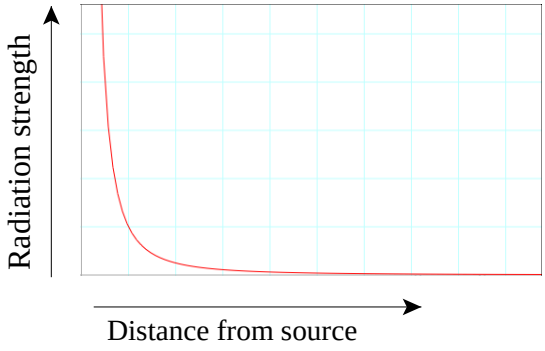
[1] Cytyc asserts claims 1, 2, 3, 4, 8, and 12. Claim 1 is an apparatus claim and the only independent claim of the '813 patent. Claims 2, 3, and 12 depend directly from claim 1. Claim 4 depends from claim 3, and claim 8 depends from claim 2. The following is a graphic representation of the relationship of the asserted claims:



claims of the '204 patent[2]. The application for the '204 patent was filed as a continuation-in-part of the '813 patent; the former purports to incorporate by reference the latter. '204 patent, col. 1, ll. 10-11. The parties seek construction of eight terms or phrases from the '813 patent and twenty-one terms or phrases from the '204 patent.

I. BACKGROUND

The patents-in-suit are directed to methods and apparatus for treatment of proliferative tissue diseases. The prior art discloses that a radiation source can be implanted at a tumor site to irradiate any remaining diseased tissue; this process is known as interstitial brachytherapy. The parties agree that for the purposes of this suit, the strength of radiation may be assumed to decrease with the square of the distance from the radiation source. The graph of the equation $y = 1 / x^2$ thus can be used as an approximation of the relationship between the radiation strength and distance. The graph, shown below, illustrates that the radiation strength close to the radiation source is disproportionately higher than that at a relatively small distance away from the radiation source.

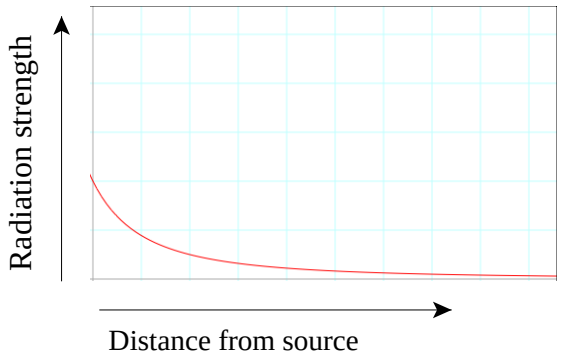


[2] Cytyc asserts claims 1, 2, 3, 4, 8, 16, 17, 18, 19, 20, 21, 23, 24, 25, 26, 30, 32, 34, 35, and 36 of the '204 patent. Claims 1 and 36 are the only independent apparatus claims. From claim 1 depend claims 2, 16, and 17. From claim 2 depend claims 4, 8, and 18. Claims 19, 32, and 34 are independent method claims. Claims 20, 21, 23, and 24 all depend from claim 19. Claim 25 depends from claim 24, and claim 26 depends from claim 25. Claim 30 also depends from claim 24. Claim 35 depends from claim 34. The following is a graphic representation of the relationship of the asserted claims:

```
   1          36          19          32          34
  /|\                    /  /  \  \                |
 2 16 17              20 21 23 24                35
/|\                          /  \
4 8 18                     25  30
                           /
                          26
```

This shows one of the problems encountered in radiation therapy, namely, that tissue close to the radiation source may get more radiation than a physician would prefer. When using interstitial therapy, a physician may wish to give all tissue within a certain distance—say, for example, 3 centimeters—from the tumor site a certain dose of radiation. However, tissue closer to the tumor site—say, 1 centimeter—will receive a much higher dose of radiation because of the inverse-square relationship. This means that healthy tissue near the tumor site may be killed by the radiation, which is an undesirable result.

Following the teachings of the patents-in-suit, the very high levels of radiation near the source can be avoided by simple mechanical means. Surrounding the radiation source on all sides with empty space (or some material other than living tissue) prevents the highest levels of radiation from affecting living tissue, giving the tissue a radiation dose profile that looks something like this:



II. ANALYSIS

A. Terms of the '813 patent

"Inner spatial volume"

Cytyc's proposed construction	*Xoft's proposed construction*
A region of space surrounded by an outer spatial volume that is defined by a closed inflatable chamber	Inner balloon in two-balloon device or spherical solid radionuclide in one-balloon device

The summary of the invention provides that

> it is possible to deliver a desired radiation dose at a predetermined radial distance from a source of radioactivity by providing a first spacial[3] volume at the distal end of a catheter and a second spacial volume defined by a surrounding of the first spatial

[3] Presumably all occurrences of "spacial" in the '813 patent should be read as "spatial."

> volume by a polymeric film wall where the distance from the spatial volume[4] and the wall is maintained substantially constant over their entire surfaces. One of the inner and outer volumes is filled with either a fluid or a solid containing a radionuclide(s) while the other of the two volumes is made to contain either a low radiation absorbing material, e.g., air or even a more absorptive material, such as an x-ray contrast fluid. Where the radioactive material comprises the core, the surrounding radiation absorbing material serves to control the radial profile of the radioactive emissions from the particular one of the inner and outer volumes containing the radionuclide(s) so as to provide a more radially uniform radiation dosage in a predetermined volume surrounding the outer chamber. Where the core contains the absorbent material, the radial depth of penetration of the radiation can be tailored by controlling the core size.

'813 patent, col. 1, l. 50-col. 2, l. 3. The first two claims of the '813 patent read:

> 1. Apparatus for delivering radioactive emissions to a body location with a uniform radiation profile, comprising:
>
> (a) a catheter body member having a proximal end and distal end;
>
> (b) an inner spatial volume disposed proximate the distal end of the catheter body member;
>
> (c) an outer, closed, inflatable, chamber defined by a radiation transparent wall affixed to the body member proximate the distal end thereof in surrounding relation to the inner spatial volume with a predetermined constant spacing between said inner spatial volume and the radiation transparent wall;
>
> (d) a material containing a radionuclide(s) disposed in one of the inner spatial volume and outer chamber; and
>
> (e) means disposed in the other of the inner spatial volume and outer chamber for rendering uniform the radial absorbed dose profile of the emissions from the one of the inner spatial volume and outer chamber containing the radionuclides.
>
> 2. The apparatus as in claim 1 wherein said inner spatial volume is an inner closed, chamber defined by a further radiation transparent wall.

'813 patent, col. 4, ll. 32-54. Since all claims of this patent other than claim 1 depend from claim 1, construction of "inner spatial volume" is critical.

In most embodiments of the invention disclosed in the patent specification, the inner spatial volume is a region of space surrrounded by an outer spatial volume that is defined by a closed inflatable chamber. *See* '813 patent, col. 2, ll. 44-63; col. 3, ll. 9-16, 42-48; col. 4, ll. 16-20; figs. 1,

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[4] Presumably this "spatial volume" should be taken to be the first spatial volume, which would mean that the polymeric film wall forms the outer boundary of the second spatial volume and that the second spatial volume is of a uniform thickness on all sides of the first spatial volume. Such a reading would comport with claim 1(c).

3-5. However, the patentee drafted the claims in such a way as to make clear that the inner spatial volume was not necessarily so limited:

> Those skilled in the art will appreciate that instead of having the inner spatial volume **30** defined by a generally spherical polymeric film wall as at **32**, the catheter body member **12** may have a solid spherical radiation emitting material in which event that solid sphere would be surrounded with the outer spherical wall **36** with the spatial volume therebetween occupied by a radioactive ray absorbent material, such as air, water or a contrast material.

'813 patent, col. 2, ll. 55-63.

Although somewhat awkwardly worded, the language of the patent allows for the inner volume to be defined by something other than a region enclosed by a polymeric wall. As Cytyc points out, Xoft's construction conflates the boundary of the volume with the volume itself. Cytyc's proposed construction, however, is a paraphrasing of the language of claim 1 that only clarifies a little the language of the patent. Furthermore, Cytyc's proposed construction would exclude an inner volume defined by a solid sphere, and thus cannot be correct.

Xoft objects that an abstract concept like a region of space cannot be part of an apparatus. Xoft is correct. However, the language of the patent does not imply that the inner volume is ever defined by something other than a physical object. In all embodiments of the invention disclosed in the '813 patent, the boundary of the inner volume is either a polymeric film wall or the edge of a solid sphere. Furthermore, it would seem difficult to fill one volume with radioactive liquid and the other with another fluid if the two volumes were not separated by some structure (which would necessarily be the outer boundary of the inner spatial volume.) *See* '813 patent, col. 1, ll. 57-62. The patent is even entitled "Double-Wall Balloon Catheter for Treatment of Proliferative Tissue." Xoft's expert, Dr. Lovoi, acknowledged that an "inner spatial volume" is a volume that is inside another volume. Lovoi Dep. at 101:25-102:7. The court defines "inner spatial volume" as "a region of space surrounded by an outer spatial volume and either enclosed by a polymeric film wall or defined by the edge of a solid radionuclide sphere."

Claim Language	***Court's Construction***
"inner spatial volume"	a region of space surrounded by an outer spatial volume and either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide sphere

"Outer, closed, inflatable chamber"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required)	Inflatable balloon, i.e., deflated balloon

Part (c) of claim 1 explains that the "outer, closed, inflatable chamber" is "defined by a radiation transparent wall affixed to the body member proximate the distal end thereof in surrounding relation to the inner spatial volume with a predetermined constant spacing between said inner spatial volume and the radiation transparent wall." '813 patent, col. 4, ll. 40-45. The preferred embodiment recites a similar structure: "Surrounding the spatial volume **30** is an outer chamber **34** defined by an outer polymeric film wall **36** that is appropriately spaced from the wall **32** of the inner chamber **30** when the two chambers are inflated or otherwise filled and supported." '813 patent, col. 2, ll. 37-41. There is no support in the patent for Xoft's argument that "outer, closed, inflatable chamber" should be limited to only a balloon in a deflated state. The court will therefore adopt Cytyc's proposal and not otherwise define this term.

Claim Language	***Court's Construction***
"outer, closed, inflatable chamber"	outer, closed, inflatable chamber

"Predetermined constant spacing"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required)	(indefinite)

"Predetermined constant spacing between said inner spatial volume and radiation transparent wall"

Cytyc's proposed construction	*Xoft's proposed construction*
The spacing between the inner spatial volume and the radiation transparent wall of the outer, closed, inflatable chamber, when inflated, can be made constant in all directions if the outer chamber is spherical, or constant along a radial plane if the outer chamber is not spherical	(indefinite)

Xoft argues that the '813 patent is indefinite because it does not disclose how one "predetermines" the amount of spacing. Xoft points out that the spacing between the edges of the inner and outer volumes may change as parts of the apparatus are inflated or deflated, so the spacing is not constant. Cytyc's expert explained that "predetermined constant spacing" means that "the

spacing between the inner spatial volume and the wall of the outer inflatable chamber can be made constant in all directions if the outer chamber is spherical, or constant along a radial direction if non-spherical, whenever the outer chamber is inflated." Su Decl. (dkt. # 49), Ex. D (Verhey Decl.) at 7 (citations omitted). Cytyc also argues that "[o]ne skilled in the art knows how to determine an appropriate 'predetermined constant spacing' and Xoft provides no evidence, testimony, or case law to the contrary. Xoft cannot possibly show that the term is indefinite by clear and convincing evidence." Reply Br. (dkt. # 53) at 15.

Because 35 U.S.C. § 282 gives a patent "a statutory presumption of validity," a challenger bears the burden of proving "by clear and convincing evidence" that a patent is invalid. *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1336-37 (Fed. Cir. 2006). "[P]atent documents need not include subject matter that is known in the field of the invention." *S3 Inc. v. NVIDIA Corp.*, 259 F.3d 1364, 1371 (Fed. Cir. 2001). From the testimony of Dr. Verhey, it appears that one skilled in the art would know how to "predetermine" the amount of spacing.[5] *See* Tr. at 56-61, 85-89. Xoft offered no evidence suggesting otherwise. As the burden of proof is Xoft's, its indefiniteness argument necessarily fails given the absence of supporting evidence. The court will therefore adopt Cytyc's proposed construction of "predetermined constant spacing between said inner spatial volume and radiation transparent wall" modified only to make the definition easier to understand. A separate construction for "predetermined constant spacing" is not necessary.

Claim Language	***Court's Construction***
"predetermined constant spacing"	(no construction necessary)
"predetermined constant spacing between said inner spatial volume and radiation transparent wall"	spacing predetermined by one skilled in the art between the wall or edge of the inner spatial volume and the radiation transparent wall of the outer, closed, inflatable chamber, when inflated, which is constant in all directions if the outer chamber is spherical, or constant along a radial plane if the outer chamber is not spherical

[5] Xoft argues that the size of the cavity determines the size of the apparatus when fully inflated, but this alone does not determine the spacing between the inner spatial volume and the wall of the outer chamber.

"Rendering uniform"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required)	Making the same, i.e., causing to have the same value or characteristic at all points.

"Means . . . for rendering uniform the radial absorbed dose profile of the emissions"

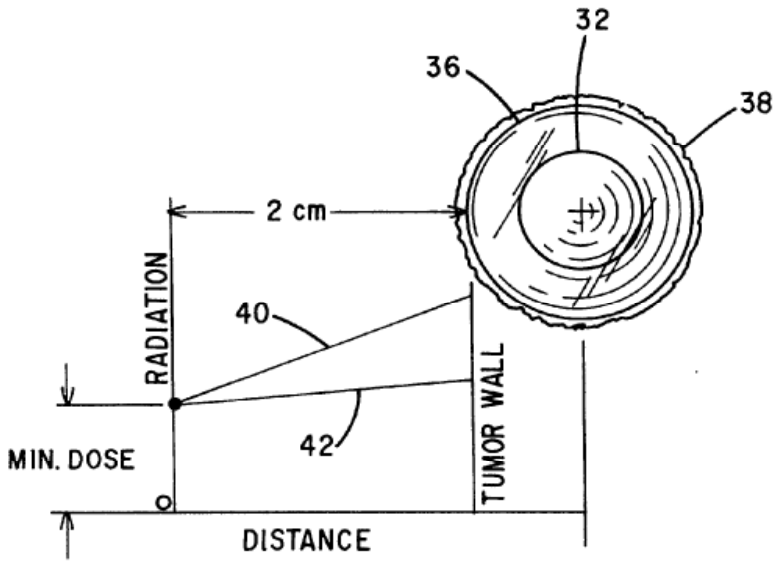
Cytyc's proposed construction	*Xoft's proposed construction*
Function: Modifying the ratio of the absorbed dose at a depth of interest in the target tissue to the absorbed dose at the surface of the tissue. Structure: A radiation absorbing or attenuating material, *e.g.*, air, x-ray contrast fluid, contrast media used in angiography, water, a gas, or barium sulfate.	Function: Making the dose along a radius extending from the radionuclide outwardly from the outer chamber wall the same at every point on the radius. Structure: No such means disclosed in '813 patent, means for making more uniform disclosed as substance within outer chamber.

Xoft's argument is that "uniform" must be taken literally, and the apparatus must produce radiation that does not decrease in strength with increasing distance from the source.[6] The parties do not dispute that Xoft's construction would require a physical impossibility; the strength of radiation necessarily decreases with distance from its source. Xoft, however, seeks to interpret "uniform" in a vacuum. The meaning of a particular word in a claim must be interpreted in light of the rest of the patent. *Ekchian v. Home Depot, Inc.*, 104 F.3d 1299, 1303 (Fed. Cir. 1997).

While the patent could have been drafted with more clarity, it is readily apparent that the patentee did not contemplate absolute uniformity. Figure 4 of the patent (reproduced below) is a comparison between the distance versus radiation dose plots of two scenarios. Line **40** shows the radiation dose that would result if chamber **36** were filled with a radioactive fluid. '813 patent, col. 3, ll. 20-24. Line **42** shows the radiation dose that would result if, following the teachings of the patent, the same radioactive fluid were contained only in chamber **32**. '813 patent, col. 3, ll. 24-28. As explained in the patent, "Comparing the plots **40** and **42**, by providing the concentric arrangement depicted, the absorbed dose profile in the space between the 2 cm site and the wall of the outer balloon is maintained much more uniform, thus preventing over-treatment of body tissue at

[6] Xoft also stated that it would "submit a Motion for Summary Judgment on this issue prior to the conduct of the *Markman* hearing," Responsive Br. (dkt. # 50) at 14, but did not do so.

or close to the outer wall **36** of the instrument." '813 patent, col. 3, ll. 28-33.



The patentee obviously did not expect absolute uniformity of radiation dosing. To interpret "uniform" in the manner urged by Xoft would go against the clear intent of the patentee. In *Bausch & Lomb, Inc. v. Barnes-Hind/Hydrocurve, Inc.*, 796 F.2d 443 (Fed. Cir. 1986), the defendant made a similar argument regarding the patentee's use of the term "smooth" with respect to the edges of contact lenses. The Federal Circuit looked to the intrinsic evidence and found that "smooth" did not mean absolutely ridge free but rather that it meant "smooth enough to serve the inventor's purposes, *i.e.*, not to inflame or irritate the eyelid of the wearer or be perceived by him at all when in place." *Id.* at 450. In this case, the inventor's purpose was to deliver radiation more uniformly than had previously been done, "thus preventing over-treatment of body tissue at or close to the outer wall . . . of the instrument." '813 patent, col. 3, ll. 28-32. The court will therefore define "rendering uniform" to mean to make the absorbed dose of radiation more uniform in order to prevent over-treatment of body tissue at or close to the outer wall of the instrument.

Since limitation language "means . . . for rendering uniform the radial absorbed dose profile of the emissions" is in means-plus-function format, the function must be construed and the corresponding structure or its equivalent identified in the specification. *BBA Nonwovens Simpsonville, Inc. v. Superior Nonwovens, L.C.C.*, 303 F.3d 1332, 1343 (Fed. Cir. 2002). As discussed, Xoft's definition of the function requires absolute uniformity which is not possible and which is not what the patent requires or the inventor intended. Cytyc's proposed definition construes the function as "modifying the ratio of the absorbed dose at a depth of interest in the target tissue to

the absorbed dose at the surface tissue." Although this appears to be a function of the invention, Cytyc's definition is too broad because it encompasses absorbed doses at the surface tissue that are not substantially uniform to absorbed doses at the target tissue. In other words, Cytyc's definition would not only encompass the radiation dose profile of line **42** above, but would also encompass the radiation doese profile of line 40. Furthermore, all radiation dose profiles between line 40 and line 42 that result in over-treatment of the surface tissue would also be included under Cytyc's definition. A more accurate construction of the function would require the absorbed dose at the target tissue and the absorbed dose at the surface tissue to be more uniform to prevent over-treatment of the surface tissue. Thus, the court defines the function of the "means . . . for rendering uniform the radial absorbed dose profile of the emissions" as making the absorbed dose of radiation more uniform to prevent over-treatment of body tissue at or close to the outer wall of the instrument.

Cytyc also identifies a radiation-absorbing or -attentuating material as the corresponding structure. At the claim construction hearing, Xoft argued that the uniformity of the radiation dose curve is solely affected by distance from the radiation source; the parties agree that this is true. *See* Tr. at 60-61. Although the composition of the material is not critical to the function, the radiation-absorbing or -attenuating material provides the distance necessary for achieving the uniformity in radiation dose curve. Thus, the court construes the language consistently with Cytyc's position.

Claim Language	***Court's Construction***
"rendering uniform"	to make the absorbed dose of radiation more uniform to prevent over-treatment of body tissue at or close to the outer wall of the instrument
"Means . . . for rendering uniform the radial absorbed dose profile of the emissions"	Function: Making the absorbed dose of radiation more uniform to prevent over-treatment of body tissue at or close to the outer wall of the instrument. Structure: A radiation absorbing or attenuating material, *e.g.*, air, x-ray contrast fluid, contrast media used in angiography, water, a gas, or barium sulfate or their equivalents.

"The radioactive material"

Cytyc's proposed construction	*Xoft's proposed construction*
The material of claim 1 containing a radionuclide.	(indefinite)

Claim 8 of the patent covers "[t]he apparatus as in claim 2 wherein the inner chamber contains the radioactive material." Claim 2 depends from claim 1. The parties dispute whether "a material containing a radionuclide(s)" suffices as an antecedent basis for "the radioactive material." It is readily apparent that the "radioactive material" in claim 8 refers back to "a material containing a radionuclide" described in claim 1, since "radionuclide" is the only radioactive material mentioned in claim 1. Anyone skilled in the art would so conclude. Xoft's contention that the term "radioactive material" is indefinite because it contains no antecedent basis is without merit. Xoft offers no authority suggesting that the antecedent basis of a term used in a dependent claim must be stated in identical words.[7] The court, therefore construes "the radioactive material" in claim 8 to be the "radionuclide(s)" referred to in claim 1.

Claim Language	***Court's Construction***
"The radioactive material"	The material of claim 1 containing a radionuclide.

"A plurality of radioactive solid particles placed at predetermined locations within the inner spatial volume to provide a desired composite radiation profile"

Cytyc's proposed construction	*Xoft's proposed construction*
A plurality of radioactive solid particles placed at pre-determined locations within the inner spatial volume to provide a desired dose profile that is the sum of the radiation profiles of the plurality of particles.	Static array of solid radioactive particles each placed in a single location and mounted on distal ends of separate wires. Desired composite radiation profile" is indefinite.

Claim 12 of the patent is directed to "[t]he apparatus as in claim 1 wherein the material containing a radionuclide comprises a plurality of radioactive solid particles placed at predetermined locations within the inner spatial volume to provide a desired composite radiation profile." Xoft argues claim 12 is indefinite on two grounds: first, that "desired composite radiation profile" is not

[7] At the *Markman* hearing, Xoft stated that it would provide a citation to such supporting authority. Tr. at 64. Xoft, however, has not done so.

defined, and second, that "inner spatial volume" is indefinite because no physical structure bounds it. The court rejects Xoft's second argument for the reasons given when construing "inner spatial volume" above. The court rejects Xoft's first argument because it presents no evidence that one skilled in the art would not understand "desired composite radiation profile."[8] Cytyc's proposed construction does not clarify the meaning of claim 12. However, since the language is understandable as is, no construction of "a plurality of radioactive solid particles placed at predetermined locations within the inner spatial volume to provide a desired composite radiation profile" is necessary or appropriate.

Claim Language	*Court's Construction*
"A plurality of radioactive solid particles placed at predetermined locations within the inner spatial volume to provide a desired composite radiation profile"	(no construction needed)

B. Terms of the '204 patent

Claim 1 of the '204 patent is similar to claim 1 of the '813 patent. Claim 1 of the '204 patent describes:

> An interstitial brachytherapy apparatus for delivering radioactive emissions to an internal body location comprising:
>
> (a) a catheter body member having a proximal end and distal end;
>
> (b) an inner spatial volume disposed proximate to the distal end of the catheter body member;
>
> (c) an outer spatial volume defined by an expandable surface element disposed proximate to the distal end of the body member in a surrounding relation to the inner spatial volume; and
>
> (d) a radiation source disposed in the inner spatial volume and generating a three-dimensional isodose profile that is substantially similar in shape to the expandable surface element.

[8] It would seem that for one skilled in the art, it would be a relatively simple matter to add up the individual radiation profiles of individual particles. *See* Tr. at 75-76.

"Interstitial"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required)	Site in natural or surgically created cavity in body.

"Brachytherapy"

Cytyc's proposed construction	*Xoft's proposed construction*
Radiation therapy delivered by a spatially confined radiation source at or near the site of the diseased tissue.	Radiation therapy delivered by a spatially confined radionuclide at or near a tumor or other proliferative tissue disease site.

"Interstitial brachytherapy"

Cytyc's proposed construction	*Xoft's proposed construction*
Brachytherapy applied directly to the interspaces of a body tissue, where the interspaces are not naturally occurring.	Radiation therapy delivered by a spatially confined radionuclide at or near a tumor site in a natural or surgically created cavity in a body.

Cytyc argues that "interstitial" and "brachytherapy" should be constructed together; Xoft seeks a separate construction for each word. Cytyc also complains that Xoft seeks to limit "brachytherapy" to radionuclides, arguing that the definition should encompass any radiation source. However, the patent provides a clear definition of "brachytherapy": "The term 'brachytherapy,' as used herein, refers to radiation therapy delivered by a spatially confined radioactive material inserted into the body at or near a tumor or other proliferative tissue disease site." '204 patent, col. 1, ll. 30-33. Here, the patentee clearly acted as his own lexicographer, and Cytyc's arguments for a broader definition do not acknowledge this clear definition. The court construes "brachytherapy" to mean "radiation therapy delivered by a spatially-confined radioactive material inserted into the body at or near a tumor or other proliferative tissue disease site."[9]

Xoft argues that "interstitial" means any body cavity, while Cytyc argues that "interstitial" should be limited to only non-naturally-occurring cavities. As Xoft points out, one medical dictionary defines "interstitial" as "1. Placed or lying between. 2. Pert. to

[9] This definition does not resolve the parties' dispute over whether "radioactive material" should be read to encompass only "radionuclides" (as Xoft wishes) or any "radiation source" (as Cytyc urges). As the parties have separately sought construction of "radioactive material," the court will address construction of that phrase below.

interstices or spaces within an organ or tissue." TABER'S CYCLOPEDIC MEDICAL DICTIONARY, 1007 (Clayton M. Thomas, ed., 17th ed. 1993). Although not cited by the parties, a British oncology text indicates that "interstitial" has a particular meaning in the field of the invention:

> Two main techniques are used for the delivery of radiation which is given either as an external beam or as short range radiation from an implanted radioactive source. External beam radiation usually involves megavoltage produced by linear accelerator as photons or electrons or from cobalt sources in the form of relative low energy X-rays or gamma rays. The latter are often used to treat relatively superficial lesions such as basal cell carcinoma or recurrences within the skin. High energy radiation can be used to treat deeply located lesions such as prostatic carcinomas without delivering an excessive dose to adjacent normal tissue. . . .
>
> Interstitial implant irradiation gives a high local dose to the tumour and usually employes sources such as radium, iridium, or caesium used in the form of needles or wires implanted in the tumour. This technique is widely used in the treatment of head and neck cancers to deliver a high tumour dose without irradiation to sensitive organs such as the lens of the eye or the spinal cord.

I.S. Fentiman, *The local Treatment of Cancer*, INTRODUCTION TO THE CELLULAR & MOLECULAR BIOLOGY OF CANCER, 434, 446 (L.M. Franks & N.M. Teich, eds., 2d ed. 1991).

However, Cytyc points out that regardless of any generally-accepted meaning of "interstitial" in the field of the invention, the patentee limited "interstitial" during prosecution to refer to only surgically-created cavities (and similarly defined "intercavital" to refer to natural body cavities):

> Turning to the cited prior art, the Ishiwara device comprises a thermotherapeutic apparatus having a catheter body member, an inner lumen surrounded by an outer lumen, and a radiation source contained within the inner lumen. . . . Ishiwara's apparatus is inserted into a body cavity. Hence, the apparatus does not provide *interstitial* radiation treatment, as Applicant's invention requires, but rather intercavital radiation treatment.

Su Decl. (dkt. # 49), Ex. C (Amendment & Resp.) at 11 (citations omitted). This is consistent with the background section of the patent, which mentions surgical cavities several times but not natural ones. '204 patent, col. 1, ll. 19, 23, 25, 63, col. 2, l. 1. Also, although the summary section does not specify what type of cavities the apparatus claims are directed to, the summary makes clear that the method claims are directed to a method that "includes surgically creating access to the proliferating tissue within a patient and surgically resecting at least a portion of the proliferating tissue to create a resection cavity within body tissue." *Id.*, col. 3, ll. 3-6.

The parties did not brief the issue of how much weight the court should afford the prosecution history in this instance.[10] The Federal Circuit has instructed that "[a]lthough prosecution history can be a useful tool for interpreting claim terms, it cannot be used to limit the scope of a claim unless the applicant took a position before the PTO that would lead a competitor to believe that the applicant had disavowed coverage of the relevant subject matter." *Schwing GmbH v. Putzmeister Aktiengesellschaft*, 305 F.3d 1318, 1324 (Fed. Cir. 2002). Here, the patentee clearly disavowed coverage of intercavitary radiation treatment when arguing to the PTO. Given the

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[10] In its recent *en banc* explanation of the evidence to be used in construing claims, the Federal Circuit devoted a paragraph to prosecution history:

> In addition to consulting the specification, we have held that a court "should also consider the patent's prosecution history, if it is in evidence." *Markman*, 52 F.3d at 980; *see also Graham v. John Deere Co.*, 383 U.S. 1, 33, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966) ("[A]n invention is construed not only in the light of the claims, but also with reference to the file wrapper or prosecution history in the Patent Office."). The prosecution history, which we have designated as part of the "intrinsic evidence," consists of the complete record of the proceedings before the PTO and includes the prior art cited during the examination of the patent. *Autogiro*, 384 F.2d at 399. Like the specification, the prosecution history provides evidence of how the PTO and the inventor understood the patent. *See Lemelson v. Gen. Mills, Inc.*, 968 F.2d 1202, 1206 (Fed. Cir. 1992). Furthermore, like the specification, the prosecution history was created by the patentee in attempting to explain and obtain the patent. Yet because the prosecution history represents an ongoing negotiation between the PTO and the applicant, rather than the final product of that negotiation, it often lacks the clarity of the specification and thus is less useful for claim construction purposes. *See Inverness Med. Switz. GmbH v. Warner Lambert Co.*, 309 F.3d 1373, 1380-82 (Fed. Cir. 2002) (the ambiguity of the prosecution history made it less relevant to claim construction); *Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1580 (Fed. Cir. 1996) (the ambiguity of the prosecution history made it "unhelpful as an interpretive resource" for claim construction). Nonetheless, the prosecution history can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be. *Vitronics*, 90 F.3d at 1582-83; *see also Chimie v. PPG Indus., Inc.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005) ("The purpose of consulting the prosecution history in construing a claim is to 'exclude any interpretation that was disclaimed during prosecution.'"), quoting *ZMI Corp. v. Cardiac Resuscitator Corp.*, 844 F.2d 1576, 1580 (Fed. Cir. 1988); *Southwall Techs., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1576 (Fed. Cir. 1995).

Phillips v. AWH Corp., 415 F.3d 1303, 1317 (Fed. Cir. 2005) (*en banc*).

intrinsic evidence is of primary importance[11] and all supports Cytyc's position, the court construes "interstitial" to mean "involving a surgically-created cavity in a body."

In light of the constructions of "interstitial" and "brachytherapy" above, no further construction of "interstitial brachytherapy" is necessary.

Claim Language	***Court's Construction***
"interstitial"	involving a surgically-created cavity in a body
"brachytherapy"	radiation therapy delivered by a spatially-confined radioactive material inserted into the body at or near a tumor or other proliferative tissue disease site
"interstitial brachytherapy"	(no construction necessary)

"Inner spatial volume"

Cytyc's proposed construction	*Xoft's proposed construction*
A region of space surrounded by an outer spatial volume that is defined by an expandable surface element	Inner balloon in two-balloon device or spherical solid radionuclide in one-balloon device.

The phrase "inner spatial volume" appears in both patents-in-suit. The parties' arguments regarding the meaning of "inner spatial volume" are similar for each patent. The relevant portions of the specification are the same, and, additionally, the '204 patent purports to incorporate by reference the '813 patent. '204 patent, col. 1, ll. 10-11. The court will therefore construe "inner spatial volume" in the '204 patent in the same manner as for the '813 patent.

Claim Language	***Court's Construction***
"inner spatial volume"	a region of space surrounded by an outer spatial volume and either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide sphere.

[11] The extrinsic evidence that Cytyc used "intercavitary" in literature and advertising in a manner that encompases the definitions of "interstitial" and "intercavitary" it advances now, *see* Tr. at 93, is of little weight in this situation. Similarly, evidence presented by Cytyc that Xoft represented to the FDA that the term "interstitial" "is a more appropriate word for a cavity that is surgically created as compared to a natural body cavity," (*see* Decl. of Henry Su Supp. Cytyc's Scupplemental Claim Construction Br., Ex. A, is not entitled to significant weight although it does suggest that one skilled in the art construes the term as Cytyc proposes.

"Outer spatial volume"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required) *or* A region of space defined by an expandable surface element and surrounding an inner spatial volume.	Balloon or cage.

The phrase "outer spatial volume" in the '204 patent is analogous to the "outer, closed, inflatable chamber" of the '813 patent. The "outer spatial volume" is also explained in a similar manner; it is "defined by an expandable surface element disposed proximate to the distal end of the body member in a surrounding relation to the inner spatial volume." '204 patent, col. 8, ll. 22-25. Xoft again confuses the concepts of a volume with the boundary of a volume. Cytyc's proposed construction is congruent with the language of claim 1 of the '204 patent, so the court will construe "outer spatial volume" as "a region of space defined by an expandable surface element and surrounding an inner spatial volume."

Claim Language	***Court's Construction***
"outer spatial volume"	a region of space defined by an expandable surface element and surrounding an inner spatial volume

"Expandable surface element"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required) *or* A device that can be expanded or inflated, such as an expandable cage or an inflatable balloon.	Deflated balloon or collapsed cage.

Xoft's basic argument is that "expandable surface element" must be a deflated structure because once something is fully inflated, it is no longer expandable. Xoft also points out that part (d) of claim 1 refers to the "isodose profile" being "substantially similar in shape to the expandable surface element" without specifying whether the expandable surface element is fully expanded. It is apparent that the patentee intended "expandable surface element" to refer to a structure whether it was fully inflated or not. Xoft's proposed construction would have this element wink out of

existence at full inflation, leaving the "outer spatial volume" unbounded and giving the "isodose profile" no shape. The court agrees with Cytyc that no construction of the term is necessary.

Claim Language	*Court's Construction*
"expandable surface element"	(no construction needed)

"Radiation source"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required)	radionuclide

The patent provides a clear definition of "brachytherapy": "The term 'brachytherapy,' as used herein, refers to radiation therapy delivered by a spatially confined radioactive material inserted into the body at or near a tumor or other proliferative tissue disease site." All asserted independent claims of the '204 patent contain the phrase "interstitial brachytherapy," which the court has construed as "radiation therapy delivered by a spatially-confined radioactive material inserted into the body at or near a tumor or other proliferative tissue disease site." Cytyc's argument that "radiation source" should not be constructed to exclude any radiation sources must be rejected; the claims clearly do not contemplate a radiation source other than "radioactive material."

There is still, however, the question of whether "radioactive material" means the same thing as Xoft's proposed construction of "radionuclide."[12] In describing the preferred embodiment, the patent says: "[t]he inner volume **30** is then filled with a material containing a predetermined radionuclide, for example, I-125, I-131, Yb-169 *or other source of radiation, such as radionuclides that emit photons, beta particles, gamma radiation, or other therapeutic rays.*" '204 patent, col. 4, ll. 9-13 (emphasis added). Since all the examples of sources of radiation given in the specification are radionuclides, the patentee appears to have intended to define "radioactive material" as "radionuclides." Cytyc argued at the *Markman* hearing that "or other therapeutic rays" could refer to other sources such as x-rays. The words "or other therapeutic rays," however, clearly refers to types

[12] The parties have agreed that "radionuclide" means "an isotope that undergoes radioactive decay."

of radionuclides. Cytyc's construction would require the patentee to have inserted the word "or" before "gamma radiation," indicating the end of the list of types of radionuclides.[13]

Dictionary definitions are consistent with construing "radiation source" as a "radionuclide." One definition of "radioactive" is "[a] descriptive term for a material made up of atoms in which radioactivity occurs." AMERICAN HERITAGE NEW DICTIONARY OF CULTURAL LITERACY (3d ed. 2006). A medical dictionary provided by Xoft defines "radioactive" as "giving off radiation as the result of the disintegration of the nucleus of an atom." MOSBY'S MEDICAL, NURSING, AND ALLIED HEALTH DICTIONARY, 1326 (Kenneth N. Anderson *et al.* eds., 4th ed. 1994). Cytyc has not presented evidence that one skilled in this art would understand "radioactive material" any differently. The court agrees with Xoft—the term "radioactive" in the context of the '204 patent does not encompass such radiation sources as x-ray tubes, and "radiation source" therefore should be taken to mean "radionuclide."

Claim Language	***Court's Construction***
"radiation source"	radionuclide

"Minimum prescribed dose"

Cytyc's proposed construction	*Xoft's proposed construction*
Minimum prescribed dose received within a target tissue for delivering therapeutic effects.	Minimum dose needed to treat cancer cells.

The parties have requested construction of the phrase "minimum prescribed dose" and point out that the term appears in claims 2, 18, 24, 32, and 36 of the '204 patent. The parties do not argue that the term should be construed differently for different claims. However, claims 2, 24, 32, and 36 contain the phrase "minimum prescribed absorbed dose," and claim 18 contains the phrase "prescribed absorbed dose." These inconsistencies seem irrelevant, however, because the parties'

[13] Cytyc also stated that this was an "Oxford comma" issue. Tr. at 137-38. However, in the sentence at issue, the Oxford comma is the one after "gamma radiation." Whether it is present does not alter the meaning of the sentence. Cytyc also argued that "we're in the land of eats, shoots and leaves." If Cytyc was referring to a book of such title, the court does not see how that would support Cytyc's argument; the theme of *Eats, Shoots & Leaves* is that punctuation should be used correctly. *See* Lynne Truss, *Eats, Shoots & Leaves: The Zero Tolerance Approach to Punctuation* (2004).

dispute is whether any such doses should be limited to treatment of cancer cells or allowed to cover any potential therapeutic effects. The court's construction of "brachytherapy" limits the claims to treatments "at or near a tumor or other proliferative tissue disease site." Xoft's proposed construction is too narrow, and Cytyc's is too broad. However, in light of the construction of "brachytherapy," no construction of "minimum prescribed dose" or similar phrases is necessary.

Claim Language	***Court's Construction***
"minimum prescribed dose"	(no construction necessary)

"Delivering a prescribed absorbed dose"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required)	(indefinite)

Xoft argues that the patent does not reveal how one goes about prescribing a dose using the device, and that the phrase "delivering a prescribed absorbed dose" is therefore fatally indefinite. The '204 patent, however, describes a tool for treating proliferative tissue disease. A patent could adequately describe and claim a new apparatus or method for making the corrective curves in contact lenses, but a description of the particular curves a patient might require would not be necessary. If those skilled in the art would know how to use the disclosed invention, describing how to use it is unnecessary—the patentee merely needs to adequately describe the invention. Since Xoft bears the burden of proving that those skilled in the art would not know how to use the tool or method described in the patent and has presented no evidence on the subject, the court rejects Xoft's contention that the phrase is indefinite. No construction is necessary.

Claim Language	***Court's Construction***
"delivering a prescribed absorbed dose"	(no construction necessary)

"The inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose"

Cytyc's proposed construction	*Xoft's proposed construction*
The inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose for delivering	(indefinite)

"The inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose"

Cytyc's proposed construction	*Xoft's proposed construction*
Configuring the inner and outer spatial volumes to provide a minimum prescribed absorbed dose for delivering therapeutic effects to a target tissue.	(indefinite)

The phrases "the inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose" and "configuring the inner and outer spatial volumes to provide a minimum prescribed absorbed dose" are not indefinite for essentially the same reasons given in the previous section. As Cytyc again appears to be attempting to impermissibly broaden its claims to capture any therapeutic effect, despite the clear limitation provided by the patentee's definition of "brachytherapy," the court also cannot adopt Cytyc's proposed construction. No construction of the disputed language is necessary in light of the court's construction of other terms in the patent.

Claim Language	***Court's Construction***
"the inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose"	(no construction necessary)
"the inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose"	(no construction necessary)

"A minimum distance outward from the outer spatial volume expandable surface"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required)	(indefinite)

Claims 2, 24, 32, and 36 all include the phrase "the target tissue being defined between the outer spatial volume expandable surface and a minimum distance outward from the outer spatial volume expandable surface."[14] Xoft asserts that "minimum distance" is indefinite in this context because the patent does not explain how the minimum distance is determined.

[14] The court believes that one skilled in the art would understand that the patentee intended to define "target tissue" as the tissue "between the outer spatial volume expandable surface and a minimum distance outward from the outer spatial volume expandable surface." Taken literally, the patent explains the physical location where the act of defining "target tissue" takes place.

Here, "minimum" does not appear to add anything to the patent. The "target tissue" is the tissue outside of the outer chamber for a fixed distance in all directions, but this fixed distance or how one determines it are not explained. It seems that one skilled in the art would know how to determine the distance. *See* Tr. at 85-89. But the patent may as well read "a short distance outward" or "a determined distance outward" or merely "a distance outward."

Cytyc claims that specification provides some guidance and that the minimum distance may in some instances be between half and one centimeter. The specification does state that

> device A can readily be configured to provide a dose in a therapeutic range, say between 40 to 60 Gray, at a distance between 0.5 and 1.0 cm from the outer spatial volume for an outer spatial volume having a diameter of 4.0 cm and being in contact with the resection cavity wall.

'204 patent, col. 6, ll. 31-35. However, Cytyc neglects to mention that "device A" is "an interstitial brachytherapy apparatus . . . such as those employed in U.S. Pat. No. 5,429,582, having a single spatial volume **50** filled with a radioactive material in solution." '204 patent, col. 6, ll. 3-7. In any case, this discussion does not use the phrases "target tissue" or "a minimum distance outward." Nevertheless, Xoft has presented no evidence that one skilled in the art would not understand the phrase "the target tissue being defined between the outer spatial volume expandable surface and a minimum distance outward from the outer spatial volume expandable surface." Xoft has not met its burden of proving by clear and convincing evidence that this language is indefinite, and the court finds that no construction is necessary.

Claim Language	***Court's Construction***
"a minimum distance outward from the outer spatial volume expandable surface"	(no construction necessary)

"Controlled dose"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required)	(indefinite)

"To reduce or prevent necrosis in healthy tissue proximate to the expandable surface"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required)	(indefinite)

"Providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue"

Cytyc's proposed construction	*Xoft's proposed construction*
Controlling the ratio of the dose at the expandable surface of the outer spatial volume to the prescribed dose at the depth of interest in the target issue so that the dose at the expandable surface is not so high that it lethally damages cells in healthy tissue in contact with the expandable surface	(indefinite)

Xoft argues that the patent does not reveal how one goes about controlling a dose using the device and that "reducing necrosis" is a hopelessly vague concept, making the '204 patent indefinite. Xoft, however, has presented no evidence that one skilled in the art would not be able to understand the patent and has again failed to meet its burden of proof. The court will therefore adopt Cytyc's construction proposals. "Providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue" means "controlling the ratio of the dose at the expandable surface of the outer spatial volume to the prescribed dose at the depth of interest in the target issue so that the dose at the expandable surface is not so high that it lethally damages cells in healthy tissue in contact with the expandable surface."

Claim Language	***Court's Construction***
"controlled dose"	(no separate construction necessary)
"to reduce or prevent necrosis in healthy tissue proximate to the expandable surface"	(no separate construction necessary)
"providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue"	controlling the ratio of the dose at the expandable surface of the outer spatial volume to the prescribed dose at the depth of interest in the target issue so that the dose at the expandable surface is not so high that it lethally damages cells in healthy tissue in contact with the expandable surface

"Adapting the expandable surface to contact tissue surrounding the resection cavity to conform the tissue"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required)	(indefinite)

Xoft's contention that this phrase is indefinite springs from its argument that "expandable surface element" means "deflated balloon or cage." As the court has rejected Xoft's interpretation of "expandable surface element," no construction of "adapting the expandable surface to contact tissue surrounding the resection cavity to conform the tissue" is necessary.

Claim Language	***Court's Construction***
"adapting the expandable surface to contact tissue surrounding the resection cavity to conform the tissue"	(no construction necessary)

"Desired shape of the expandable surface element"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required)	(indefinite)

Xoft has again presented no evidence to back up an argument that the phrase is indefinite and therefore again fails to carry its burden of proof. No construction of "desired shape of the expandable surface element" is necessary.

Claim Language	***Court's Construction***
"desired shape of the expandable surface element"	(no construction necessary)

"Predetermined spacing"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required)	(indefinite)

"A predetermined spacing is provided between said inner spatial volume and the expandable surface element" / "A predetermined spacing between said inner spatial volume and the expandable surface element"

Cytyc's proposed construction	*Xoft's proposed construction*
The distance between the inner spatial volume and the expandable surface element is determined in advance	(indefinite)

Xoft's contention that these phrases are indefinite is based on its argument that "expandable surface element" means "deflated balloon or cage," and Xoft has again presented no evidence to back up arguments that the phrases are indefinite. No construction of "predetermined spacing" is necessary. The court will adopt Cytyc's proposals and define both of the long phrases ("a predetermined spacing is provided between said inner spatial volume and the expandable surface element" and "a predetermined spacing between said inner spatial volume and the expandable surface element") as "the distance between the inner spatial volume and the expandable surface element is determined in advance."

Claim Language	***Court's Construction***
"predetermined spacing"	(no construction necessary)
"a predetermined spacing is provided between said inner spatial volume and the expandable surface element" / "a predetermined spacing between said inner spatial volume and the expandable surface element"	the distance between the inner spatial volume and the expandable surface element is determined in advance

"Intraoperatively"

Cytyc's proposed construction	*Xoft's proposed construction*
(no construction required) *or* During the surgical operation to remove proliferative tissue.	After surgical removal of tumor but prior to closing the surgical site

At the claim construction hearing, the parties appeared to agree on the definition of "interoperatively." *See* Tr. at 140. The previous apparent disagreement revolved around whether the surgical site could be closed before insertion of the catheter apparatus. The court understands that the parties agree that the catheter must be inserted before the surgical site is closed. The '204 patent at column 7, lines 55-64, specifically refers to the catheter being inserted "[f]ollowing tumor resection, but prior to closing the surgical site."

Claim Language	***Court's Construction***
"intraoperatively"	following tumor resection, but prior to closing the surgical site

"Solid radiation source"

Cytyc's proposed construction	*Xoft's proposed construction*
A radiation source that has a fixed shape and volume, and is not deformable	Solid radionuclide

The parties' primary dispute here is whether "radiation source" encompasses more than radionuclides, which the court addressed above to limit "radiation source" to radionuclides. Cytyc presents a dictionary definition of "solid," namely, "of definite shape and volume; not liquid or gaseous," from the AMERICAN HERITAGE COLLEGE DICTIONARY, 1295 (3d ed. 1997). The court will therefore define "solid radiation source" as "a radionuclide of definite shape and volume; not liquid or gaseous."

Claim Language	***Court's Construction***
"solid radiation source"	a radionuclide of definite shape and volume; not liquid or gaseous

"The prescribed absorbed dose is delivered to the target tissue in substantially three dimensions"

Cytyc's proposed construction	*Xoft's proposed construction*
The prescribed absorbed dose is delivered to the target tissue such that all points at a given outward distance from the tissue wall will receive the same dose.	(indefinite)

Xoft contends that "prescribed absorbed dose" and "in substantially three dimensions" render "the prescribed absorbed dose is delivered to the target tissue in substantially three dimensions" fatally indefinite. The court has already rejected Xoft's argument regarding "prescribed absorbed dose."

Xoft points to Cytyc's expert's testimony that "there's no such thing as substantially three dimensions" because something is either three dimensional or not. Mulville Decl. (dkt. # 51), Ex. L (Verhey Decl.) at 153. Cytyc points to Xoft's expert's testimony that he could envision a brachytherapy apparatus that delivered 99 percent of its radiation in a plane; Cytyc claims such a flat radiation field would not be in substantially three dimensions. Though a closer question than some of Xoft's other indefiniteness contentions, the court nonetheless finds that Xoft has not shown by clear and convincing evidence that one skilled in the art would not understand "in substantially three

dimensions" in the manner put forth by Cytyc. The court therefore adopts Cytyc's proposed construction for "the prescribed absorbed dose is delivered to the target tissue in substantially three dimensions," namely, "the prescribed absorbed dose is delivered to the target tissue such that all points at a given outward distance from the tissue wall will receive the same dose."

Claim Language	***Court's Construction***
"the prescribed absorbed dose is delivered to the target tissue in substantially three dimensions"	the prescribed absorbed dose is delivered to the target tissue such that all points at a given outward distance from the tissue wall will receive the same dose

III. ORDER

1. For the reasons given above, the court adopts the following claim construction as detailed in this order.

Term or phrase	Court's construction
"inner spatial volume"	a region of space surrounded by an outer spatial volume and either enclosed by a polymeric film wall or defined by the outside surface of a solid radionuclide sphere.
"outer, closed, inflatable chamber"	outer, closed, inflatable chamber
"predetermined constant spacing"	(no construction necessary)
"predetermined constant spacing between said inner spatial volume and radiation transparent wall"	spacing predetermined by one skilled in the art between the wall or edge of the inner spatial volume and the radiation transparent wall of the outer, closed, inflatable chamber, when inflated, which is constant in all directions if the outer chamber is spherical, or constant along a radial plane if the outer chamber is not spherical
"rendering uniform"	to make the absorbed dose of radiation more uniform to prevent over-treatment of body tissue at or close to the outer wall of the instrument
"Means . . . for rendering uniform the radial absorbed dose profile of the emissions"	Function: Making the absorbed dose of radiation more uniform to prevent over-treatment of body tissue at or close to the outer wall of the instrument. Structure: A radiation absorbing or attenuating material, *e.g.*, air, x-ray contrast fluid, contrast media used in angiography, water, a gas, or barium sulfate or their equivalents.
"The radioactive material"	The material of claim 1 containing a radionuclide.
"A plurality of radioactive solid particles placed at predetermined locations within the inner spatial volume to provide a desired composite radiation profile"	(no construction needed)
"interstitial"	involving a surgically-created cavity in a body
"brachytherapy"	radiation therapy delivered by a spatially-confined radioactive material inserted into the body at or near a tumor or other proliferative tissue disease site
"interstitial brachytherapy"	(no construction necessary)

"outer spatial volume"	a region of space defined by an expandable surface element and surrounding an inner "expandable surface element"(no construction needed)
"radiation source"	radionuclide
"minimum prescribed dose"	(no construction necessary)
"delivering a prescribed absorbed dose"	(no construction necessary)
"the inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose"	(no construction necessary)
"the inner and outer spatial volumes are configured to provide a minimum prescribed absorbed dose"	(no construction necessary)
"a minimum distance outward from the outer spatial volume expandable surface"	(no construction necessary)
"controlled dose"	(no separate construction necessary)
"to reduce or prevent necrosis in healthy tissue proximate to the expandable surface"	(no separate construction necessary)
"providing a controlled dose at the outer spatial volume expandable surface to reduce or prevent necrosis in healthy tissue"	controlling the ratio of the dose at the expandable surface of the outer spatial volume to the prescribed dose at the depth of interest in the target issue so that the dose at the expandable surface is not so high that it lethally damages cells in healthy tissue in contact with the expandable surface
"adapting the expandable surface to contact tissue surrounding the resection cavity to conform the tissue"	(no construction necessary)
"desired shape of the expandable surface element"	(no construction necessary)
"predetermined spacing"	(no construction necessary)
"a predetermined spacing is provided between said inner spatial volume and the expandable surface element" / "a predetermined spacing between said inner spatial volume and the expandable surface element"	the distance between the inner spatial volume and the expandable surface element is determined in advance
"intraoperatively"	following tumor resection, but prior to closing the surgical site
"solid radiation source"	a radionuclide of definite shape and volume; not liquid or gaseous

"the prescribed absorbed dose is delivered to the target tissue in substantially three dimensions"	the prescribed absorbed dose is delivered to the target tissue such that all points at a given outward distance from the tissue wall will receive the same dose

2. The parties shall appear for a further case management conference on June 1, 2007 at 10:30 a.m. and shall file a further joint case management conference statement no later than four days prior.

DATED: 4/27/07

Ronald M. Whyte

RONALD M. WHYTE
United States District Judge

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Dated: 4/27/07

SPT
Chambers of Judge Whyte

United States District Court
For the Northern District of California

Exhibit C

DESCRIPTION

The Contura™ MLB Applicator consists of a multi-lumen catheter attached to an inflatable spherical balloon (Figure 1). Lumens are provided for attachment to commercially available HDR (High Dose Rate) remote afterloader equipment for passage of the radiation source delivery wire. Five radiation source wire lumens are provided; one central lumen located along the long axis of the Applicator and four curved lumens symmetrically offset from the central lumen. A removable stiffening stylet is positioned in the central lumen. Two proximal ports are also provided with Luer-type connectors for balloon inflation/deflation and for application of intracavitary vacuum.

The Contura™ MLB accessories provided for introduction and deployment include: trocar with split sheath, drainage catheter, three, 30 ml and one, 10 ml inflation syringes, #11 scalpel, contrast media tray, radiation lumen caps and labels (Figure 2).

Afterloader compatibility:
Model B001-45 - VariSource 200, VariSource ID and Nucletron HDR afterloaders.
Model B011-45 - GammaMedPlus afterloader (Cannot be used with GammaMed 12i)

Warning: The safety and effectiveness of the SenoRx Applicator as a replacement for whole breast irradiation in the treatment of breast cancer has not been established.

INDICATIONS FOR USE

The Contura™ MLB Applicator is intended to provide brachytherapy when the physician chooses to deliver intracavitary radiation to the surgical margins following lumpectomy for breast cancer.

CONTRAINDICATIONS

- The Applicator is not intended for use in cavities that are too small, too large and/or of shapes unable to conform to an approximately spherical, 4 to 5 cm diameter SenoRx balloon.
- The Applicator is not intended for use in patients with unusual anatomy including a highly curved rib structure and/or unequal amounts of tissue surrounding the cavity that may cause the SenoRx balloon to be asymmetrical.

WARNINGS

- Use caution when positioning the trocar tip near the chest wall or skin margin to avoid unintended tissue damage.
- Do not fill the Applicator with more than 58 ml of fluid as overfilling may result in balloon rupture and/or device failure.
- The Applicator must be pre-tested before implantation. Do not use the balloon if it is not approximately spherical and/or any leakage is detected.
- The breast cavity must be imaged before implantation to insure the Applicator will fit appropriately. Do not use if the cavity is too small or if a skin surface to balloon surface distance of less than 5 mm will result.
- To insure appropriate treatment dose distribution, the Applicator must be imaged prior to delivering each fraction of radiation to confirm correct position, balloon volume, skin spacing and conformance.
- If excessive resistance is encountered when attempting to remove the Applicator from the patient, surgical removal is recommended.

- Contrast media concentrations of less than 10% are recommended to prevent dose attenuation.
- Non-ionic contrast media is recommended for patients who are allergic to iodine-based agents.

PRECAUTIONS

- The Applicator must be used only by physicians trained in catheter implantation, radiation treatment planning and delivery.
- Metal vascular and marking clips should not be used during the lumpectomy procedure to prevent potential abrasion or puncture of the Contura™ balloon. Care should also be taken to direct suture knots and tails away from the cavity and whenever possible position tissue between the potential balloon surface and the tails.
- Store the SenoRx Applicator at room temperature (20 to 25ºC).
- Care must be taken when handling and manipulating the Contura™ balloon to prevent damage and foreign material contamination of the balloon surface.
- A scalpel should be used to incise the skin prior to inserting the trocar tip.
- Do not inject fluids into the Vacuum Port.
- Replace Luer caps and radiation lumen caps after use.
- Only clinical personnel trained in the operation of HDR afterloaders should deliver radiation using the Applicator.
- Verify that the appropriate afterloader connectors are available and function with the Applicator prior to treatment.
- Be sure that the Applicator is as straight as possible and free of sharp bends and kinks prior to connecting to the HDR afterloader.
- Inspect package before use. Discard if seal is compromised or packaging is damaged.

COMPLICATIONS

Complications that may be associated with the use of the Contura™ MLB Applicator are the same as those associated with the use of similar devices. These may include: erythema, catheter site drainage, breast pain, ecchymosis, breast fibrosis, telangiectasia, breast induration, breast seroma, breast edema, dry desquamation, dry skin, skin discoloration, parasthesia, axilllary pain, fatigue, pruritis, breast retraction, nausea, skin irritation, moist desquamation, hematoma, rash, asymptomatic fat necrosis, breast infection, breast blister and lymphedema.

HOW SUPPLIED

The Contura™ MLB Applicator and accessories are provided sterile and are intended for single patient use only.

DIRECTIONS FOR USE

- **PLACEMENT** - Refer to Figures 1 & 2

1. Use ultrasound to identify the lumpectomy cavity.
2. Open the Contura™ MLB Applicator sterile package and remove the Applicator (A) and one 30 ml Syringe (B). Remove the Inflation Port Luer Cap (C) and inject 58 ml of sterile saline into the Applicator and inspect for leaks and spherical symmetry. Discard Applicator if defective. Holding the Applicator by the connectors, with the balloon hanging vertically, completely withdraw the saline from balloon.
3. Prepare a maximum 5% contrast media/sterile saline solution in the Tray (D) provided.
4. Determine the desired point on the breast surface for the insertion of the Applicator. Inject appropriate anesthetic to the skin and pathway to the lumpectomy cavity. Make a skin incision with the scalpel at the insertion point of sufficient length to fully insert the Trocar (F) tip. Dilate the skin incision, if desired. Advance the Trocar with Split Sheath (G) into the cavity. Remove the Trocar.
5. Attach a 30 ml syringe to the Drainage Catheter (H) and drain any fluids within the cavity by inserting the Drainage Catheter through the Split Sheath and suctioning. Remove the Drainage Catheter.
6. Insert the Applicator through the Split Sheath into the cavity. Remove the Sheath.
7. Align the Radiopaque Line (I) on the catheter shaft with the skin incision.
8. Remove the stiffening Stylet (J) from the Central Source Lumen (K). Attach a red radiation source lumen Cap (L).
9. Using the syringes provided, inflate the Applicator balloon with the contrast media solution to the desired fill volume. Purge any air from the fill syringes before attaching them to the Applicator.

Desired balloon diameter	Approximate balloon fill volume
4 cm	33 ml
5 cm	58 ml

10. Replace the Luer Cap on to the Inflation Port (M).
11. Use ultrasound to confirm appropriate placement, volume and cavity conformance. Fluid and air surrounding the Applicator balloon may be aspirated with a 30 ml Syringe attached to the white Vacuum Port (N). The volume of the balloon may be adjusted through the blue Inflation Port (M). Replace Luer Caps when finished.
12. Confirm that the radiopaque line is aligned with the skin incision.
13. Apply a surgical dressing to the exit site with the catheter positioned to minimize bending.
14. Record the final balloon fill volume on the Labels provided and attach to the patient's chart.

- **RADIATION DELIVERY** - Refer to Figure 3

1. CT imaging should be used in conjunction with commercially available treatment planning software to determine the appropriate source lumens, source dwell positions and dwell times for optimized radiation delivery of a prescribed dose to the targeted treatment volume.
2. Note the orientation of the Contura™ MLB Applicator with respect to the radiopaque line on the catheter shaft. Verify correct Applicator orientation, balloon position, balloon volume, skin spacing and conformance using imaging prior to delivery of each fraction of radiation. Adjust if necessary.
3. The Applicator red-capped, radiation source wire lumens are numbered '1', '2', '3', '4' and '5' and positioned as shown in Figure 3. Lumen number '1' corresponds to the offset lumen closest and parallel to the longitudinal radiopaque line (M) along the outside of the catheter. Lumen number '5' corresponds to the central lumen. Remove the red caps and use commercially available connectors to attach the source lumens to the afterloader.

Note: When using the GammaMedPlus Afterloader, the radiation source lumens of the B011-45 Applicator must first be trimmed to length using the GammaMed length cutting gauge.

4. After each treatment replace the red caps.

- **REMOVAL**

1. Remove the Contura™ MLB Applicator by first attaching a syringe to the blue Inflation Port and deflating the balloon.

   Note: If difficulty is encountered deflating balloon with syringe:

   1) Re-attach syringe and securely rotate clockwise to completely activate the valve. If the balloon, still does not deflate, then
   2) Cut the blue Inflation Port tubing. The saline/contrast contents of the balloon will now drain from the end of the cut tubing

2. Rotate and withdraw (unscrew) the Applicator from the cavity.

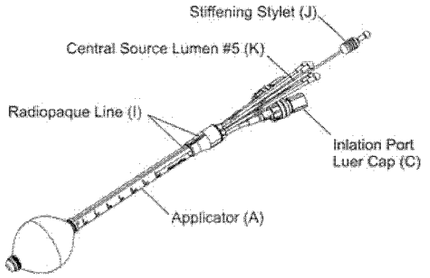

Figure 1: **SENORX APPLICATOR**

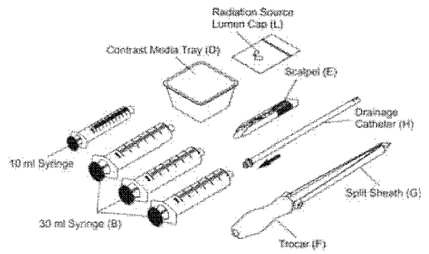

Figure 2: **ACCESSORIES**

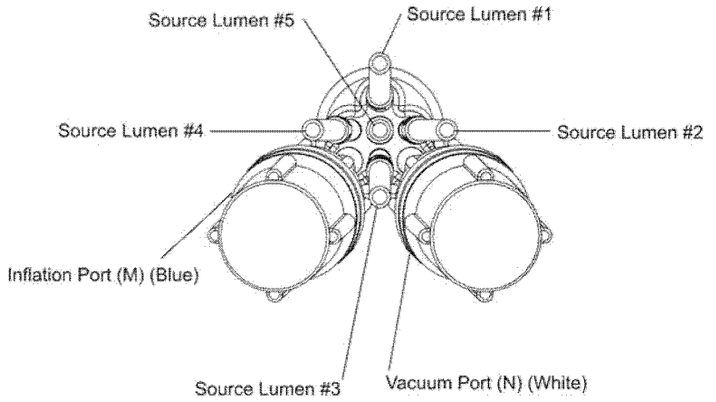

Figure 3: **SOURCE WIRE LUMEN ORIENTATION**

This product is covered by one or more of the following U.S. Patents: 6,923,754; 6,955,641; 7,241,178. Other domestic and foreign patents pending.

EXPLANATION OF SYMBOLS ON THE PACKAGE

REF	Catalogue Number
	Use by Date
LOT	Lot Number
CONT	Contents
STERILE R	Sterile (Gamma radiation)
	Attention, See Instructions for Use
2	Do Not Reuse
	Upper Temperature Limit
	Keep away from sunlight
	Keep dry

SenoRx Inc.
Aliso Viejo, California
USA

Contura™ Multi-Lumen Balloon • MLB

MULTI-LUMEN BALLOON SOURCE APPLICATOR FOR BRACHYTHERAPY

INSTRUCTIONS FOR USE

MODELS

B001-45
B011-45

Caution: **Federal (USA) law restricts this device to sale by or on the order of a physician.**

SENORX

IU0093 Rev. E
November 2007/ECO 4022

Exhibit Q

APPLICATION

of

Paul Lubock

for

UNITED STATES LETTERS PATENT

on

VACUUM DEVICE AND METHOD FOR TREATING TISSUE ADJACENT A BODY CAVITY

Sheets of Drawings: Five (5)
Atty. Docket No.: 9619-1300

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VACUUM DEVICE AND METHOD FOR TREATING TISSUE ADJACENT A BODY CAVITY

FIELD OF THE INVENTION

[0001] This invention relates generally to the fields of medical treatment devices and methods. In particular, the invention relates to devices and methods for treating tissue surrounding a body cavity, such as a site from which cancerous, pre-cancerous, or other tissue has been removed.

BACKGROUND OF THE INVENTION

[0002] In diagnosing and treating certain medical conditions, it is often desirable to perform a biopsy, in which a specimen or sample of tissue is removed for pathological examination, tests and analysis. A biopsy typically results in a biopsy cavity occupying the space formerly occupied by the tissue that was removed. As is known, obtaining a tissue sample by biopsy and the subsequent examination are typically employed in the diagnosis of cancers and other malignant tumors, or to confirm that a suspected lesion or tumor is not malignant. Treatment of cancers identified by biopsy may include subsequent removal of tissue surrounding the biopsy site, leaving an enlarged cavity in the patient's body. Cancerous tissue is often treated by application of radiation, by chemotherapy, or by thermal treatment (e.g., local heating, cryogenic therapy, and other treatments to heat, cool, or freeze tissue).

[0003] Cancer treatment may be directed to a natural cavity, or to a cavity in a patient's body from which tissue has been removed, typically following removal of cancerous tissue during a biopsy or surgical procedure. For example, U.S. Patent

5,429,582 to Williams, U.S. Patent 5,913,813 to Williams et al., U.S. Patent 5,931,774 to Williams et al., U.S. Patent 6,022,308 to Williams, U.S. Patent 6,083,148 to Williams, and U.S. Patent 6,413,204 to Winkler et al., the disclosures of which are all hereby incorporated by reference in their entireties, describe devices for implantation into a cavity resulting from the removal of cancerous tissue which can be used to deliver cancer treatments to surrounding tissue. One form of radiation treatment used to treat cancer near a body cavity remaining following removal of tissue is "brachytherapy" in which a source of radiation is placed near to the site to be treated.

[0004] Williams and coworkers describe implantable devices for treating tissue surrounding a cavity left by surgical removal of cancerous or other tissue that includes an inflatable balloon constructed for placement in the cavity. Such devices may be used to apply one or more of radiation therapy, chemotherapy, and thermal therapy to the tissue surrounding the cavity from which the tissue was removed. The balloon may be filled with a treatment fluid delivered via a conduit from a receptacle, syringe, or other means, or may receive a solid radiation source placed within the balloon. Thus, radiation treatment may be applied to tissue adjacent the balloon by placing radioactive material such as radioactive "seeds" within the balloon, or by filling the balloon with a liquid or slurry containing radioactive material. Multiple treatments may be applied simultaneously. For example, radioactive seeds may be placed within the balloon effective to irradiate tissue surrounding the balloon, and the balloon filled with a hot fluid at the same time to provide thermal treatment. After a suitable time, the hot fluid and/or the radioactive seeds may be removed. Such treatments, combined or otherwise, may be repeated if desired.

[0005] For example, a "MammoSite® Radiation Therapy System" (MammoSite® RTS, Proxima Therapeutics, Inc., Alpharetta, GA 30005 USA) includes a balloon catheter with a radiation source that can be placed within a tumor resection cavity in a breast after a lumpectomy. It can deliver a prescribed dose of radiation from inside the tumor resection cavity to the tissue surrounding the original tumor. The radiation source is typically a solid radiation source; however, a liquid radiation source may also be used with a balloon catheter placed within a body cavity (e.g., Iotrex®, Proxima Therapeutics, Inc.). The radiation source may be removed following each treatment session, or may remain in place as long as the balloon remains within the body cavity. Inflatable treatment delivery devices and systems, such as the MammoSite® RTS and similar devices and systems (e.g., GliaSite® RTS (Proxima Therapeutics, Inc.)), are useful to treat cancer in tissue adjacent a body cavity.

[0006] However, radiation, chemotherapy, thermal treatment, and other cancer treatments often have deleterious effects on healthy tissue in addition to the desired effects on cancerous tissue. In such treatments, care must be taken to direct the maximum treatment effects to diseased tissue while minimizing its delivery or effects on healthy tissue. For example, radiation treatment may be most effective when all surrounding tissue regions receive the same dose of radiation, and where the radiation dosage received by more distant tissue is as small and as uniform as possible. However, tissue cavities typically are not uniform or regular in their sizes and shapes, so that differences in dosages applied to different regions of surrounding tissue, including "hot spots" and regions of relatively low dosage, often result from radiation treatment.

[0007] Thus, there is need in the art for improved devices and methods for delivering cancer treatment to a cavity site within a patient's body.

SUMMARY OF THE INVENTION

[0008] The invention provides assemblies, devices, systems, and methods for treating tissue adjacent a body cavity, such as a cavity formed by the removal of tissue from a patient. In methods and devices having features of the invention, vacuum is applied effective to draw tissue towards a treatment assembly placed within the body cavity. Assemblies and devices embodying features of the invention include a vacuum delivery element configured to apply a vacuum. A vacuum delivery element may include a vacuum conduit, and may further include a vacuum port. A vacuum delivery element may be configured to at least partially surround or enclose a treatment assembly. A treatment assembly may be configured to deliver a treatment, such as radiation therapy, chemotherapy, thermal therapy, or other treatment, to tissue adjacent a body cavity. A treatment assembly may include a treatment delivery element configured to contain a treatment material, such as a radioactive source. A treatment assembly may include an inflatable balloon, which may be disposed at least in part around a treatment delivery element.

[0009] Assemblies and devices embodying features of the invention may include a vacuum delivery element such as a sheath or a balloon configured to provide vacuum effective to apply suction to tissue adjacent the assemblies and devices. Vacuum delivery elements are preferably configured to apply suction to tissue adjacent a treatment delivery assemblies, such as an inflatable treatment delivery device. Suction

is effective to draw surrounding tissue close to the surface of a treatment assembly, or to a vacuum delivery element (such as a sheath or balloon) at least partially surrounding or enclosing a treatment assembly, so as to shape the tissue lining the body cavity for optimal treatment. Treatment may be by, e.g., radiation therapy, chemotherapy, thermal therapy, or other treatment modality supplied by the device. A treatment assembly may include an inflatable treatment assembly such as an inner balloon assembly configured to be at least partly enclosed by a vacuum delivery element such as a sheath or balloon. A sheath may be configured to at least partly enclose a balloon temporarily, following placement over or around an inner balloon. A balloon may be configured to at least partly enclose a balloon permanently following placement over or around an inner balloon.

[0010] Devices may further include an enclosure assembly (which may comprise a sheath assembly or a balloon assembly) comprising a vacuum conduit and a fluid-permeable enclosure wall (e.g., a sheath wall or a balloon wall) configured to partly or completely enclose an inner balloon assembly. Such an enclosure assembly may be effective to provide vacuum and a vacuum path to an intermediate space outside the inner balloon assembly. An intermediate space may include a space disposed between the inner balloon assembly and a sheath assembly or an outer balloon assembly. The enclosure assembly is preferably operatively connected to a vacuum conduit effective to provide vacuum to the intermediate space. Systems having features of the invention include such devices and further include a vacuum source configured to operatively connect with the vacuum conduit. In embodiments of devices having features of the invention, a fluid-permeable enclosure wall may have a hole or multiple holes

configured to allow passage of fluid, may be made with a fluid-permeable material, such as a fluid-permeable woven material, or may be otherwise fluid-permeable. The space between the inner balloon and the enclosure may be prevented from collapse, even in the presence of suction from a vacuum delivered via the vacuum conduit, by separation elements disposed on the inner balloon wall, or on the enclosure wall, or both. In alternative embodiments, separation elements disposed within an intermediate space may be independent of both the inner balloon wall and the enclosure wall.

[0011] An embodiment of a device for treating tissue adjacent a body cavity having features of the invention further comprises an inner balloon assembly, which may include or be operatively connected with an inflation conduit configured to allow passage of a fluid. Devices may also have an inner balloon comprising a distensible inner balloon wall defining an internal lumen. Such an inner balloon may be operatively connected to an inflation conduit so as to allow for passage of fluid through an inflation conduit and into the internal lumen so as to inflate the inner balloon with the fluid.

[0012] An enclosure wall preferably comprises a flexible material, more preferably an elastic flexible material, although in embodiments of the invention, an eneclosure wall may comprise an inelastic flexible material. In embodiments of devices and systems having features of the invention, an enclsoure wall comprises a polymer, such as biocompatible polymer, preferably a radiation-resistant polymer. Suitable polymers include polyolefins such as polyethylene and polypropylene, polyurethanes, polyester, polyvinylchloride, polystyrene, thermoplastic polymers such as C-Flex® (Consolidated Polymer Technologies, Inc., Clearwater FL 33762), block polymers such as Kraton™ (Kraton Polymers, Houston TX 77208), an ionomer such as Surlyn®

(Dupont, Wilmington DE 19880), nylon, latex rubber, and silicon rubber (e.g., SILASTIC™, Dow Corning, Midland, MI).

[0013] Devices and systems having features of the invention include inner balloon assemblies configured to enclose a treatment material, such as radioactive material, chemotherapeutic agents, and thermal treatment materials (e.g., materials having a temperature greater than about 37 °C).

[0014] The invention further provides methods for treating tissue adjacent a body cavity, comprising contacting tissue adjacent a body cavity with a sheath or an outer balloon having a fluid-permeable wall of a device having features of the invention; and applying a vacuum effective to enhance the contact between the fluid-permeable wall and the tissue. Further methods may include delivering inflation fluid to an inner balloon lumen via an inflation conduit to inflate a distensible balloon. In embodiments of the methods of the invention, the inner balloon assembly comprises a treatment assembly such as a Mammosite RTS or similar inflatable treatment delivery device. Methods may include placing a treatment material within the device, and may further include replacing the treatment material.

[0015] Body cavities are typically not uniform in size or regular in shape. Devices, systems and methods having features of the invention utilize suction to draw tissue against the device surface within a body cavity, insuring good contact between the device and body tissue and providing control over the spacing between tissue and the device, including control over the distance from the treatment material contained within the devices. Tissue lining a body cavity that is held close to, or in contact with, devices having features of the invention forms a uniform and controlled surface, unlike

tissue lining a body cavity in which a prior art treatment device has been merely inserted, but which does not urge tissue into a desired orientation and position. The control over the distance, spacing, and amount of tissue contact provided by devices, systems and methods of the present invention offer the advantages of improved treatment tissue adjacent a body cavity. Such improvements may include more uniform dosing, reduction of "hot spots," shorter treatments due greater correlation between desired and actual dosages, and reduction in the number of locations receiving inadequate dosages.

BRIEF DESCRIPTION OF THE DRAWINGS

[0016] Figure 1 is partially cut-away perspective view of a system embodying features of the invention shown configured to deliver a treatment within a cavity in a patient's body tissue while providing vacuum effective to urge tissue into contact with an outer balloon surface.

[0017] Figure 2 is a longitudinal cross-sectional view of the system of Fig. 1 taken along line 2-2.

[0018] Figure 3 is a transverse cross-sectional view of the system of Fig. 1 taken along line 3-3.

[0019] Figure 4A is a cross-sectional view of a system of Fig. 1 showing a pie-shaped section of balloon walls between lines 4-4 for an embodiment in which an outer wall has stand-offs.

[0020] Figure 4B is a cross-sectional view of the system of Fig. 1 showing a pie-shaped section of balloon walls between lines 4-4 for an embodiment in which an inner wall has stand-offs.

[0021] Figure 5A shows a perspective view of a system embodying features of the invention in which an outer balloon assembly, in the form of a sheath, is being fitted over an inner balloon assembly.

[0022] Figure 5B shows a cross-sectional view of the assembled outer and inner balloon assemblies of Figure 5A following placement into a cavity within a breast of a patient and before inflation of the inner balloon assembly.

[0023] Figure 5C shows a cross-sectional view of the assembled outer and inner balloon assemblies of Figure 5A following inflation of the inner balloon assembly.

[0024] Figure 5D shows a cross-sectional view of the assembled outer and inner balloon assemblies of Figure 5A following application of vacuum to the lumen separating the inner balloon assembly and the outer balloon assembly, and after placement of a radioactive assembly within the inner balloon assembly.

[0025] Figure 6A is perspective view of a system embodying features of the invention including a vacuum delivery element configured to partly enclose an inner balloon assembly.

[0026] Figure 6B is a cross-sectional view of the system of Figure 6A taken along line 6B-6B.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0027] The present invention provides devices and methods for delivering a treatment, such as a cancer treatment, into a cavity within the body of an animal. For example, devices and methods having features of the invention may be used to deliver treatments into a biopsy site or into a cavity left after removal of cancerous tissue from within the body of a human patient. Vacuum is applied to tissue to enhance contact between a treatment delivery assembly within a body cavity and tissue surrounding the body cavity. A vacuum path around the treatment assembly is provided by devices, systems and methods embodying features of the invention. Vacuum may be applied to tissue via one, two, or multiple vacuum ports. A vacuum port may be a port in a vacuum delivery conduit, a hole in a sheath or balloon connected to a vacuum delivery conduit. A fluid permeable wall or portion of a fluid permeable wall may be effective to serve as a vacuum port.

[0028] Figure 1 is a perspective view of a system 10 embodying features of the invention illustrating a device 12 having an outer balloon 14 enclosing an inner balloon 16 (shown in the cut-away portion of the illustration), a shaft 18 and connector 20. Outer balloon 14 comprises a sheath assembly around inner balloon 16. Outer balloon 14 is thus an example of an enclosure assembly, and forms an enclosure wall around inner balloon 16. Outer balloon 14 comprises at least in part a fluid permeable wall; as illustrated in Figure 1, outer balloon 14 has holes 22 allowing fluid permeation into and out of balloon 14. In alternative embodiments, an outer balloon 14 may be made of woven or otherwise substantially continuous materials that are fluid permeable. In further embodiments, an enclosure wall or assembly such as an outer balloon may

comprise a net, mesh, framework, or other discontinuous structure. Holes 22 (or fluid permeable material) allows fluids to pass through outer balloon 14 into intermediate space 24 disposed outside inner balloon 16. Intermediate space 24 provides a vacuum path adjacent inner balloon 16. Where at least a portion of outer balloon 14 is disposed adjacent inner balloon 16, intermediate space 24 is disposed between outer balloon 14 and inner balloon 16.

[0029] Inner balloon 16 defines an inner lumen 26, within which a delivery shaft 28 may be at least partially contained. As shown in Figure 2, a treatment material 30 may be permanently or transiently disposed within delivery shaft 28. A probe 32 configured to move within delivery shaft 28 may be used to position treatment material 30, including to place treatment material 30 into and to retrieve placement material 30 from, within delivery shaft 28. A vacuum conduit 34 may be part of, or may be contained within, a shaft 18 and operatively connected to intermediate space 24. Shaft 18 may also include or contain an inflation conduit 36 configured to allow passage of inflation fluid into inner lumen 26. Passage of inflation fluid into inner lumen 26 is effective to inflate inner balloon 16. Inflation fluid may be any suitable fluid, either a gas or a liquid, and is typically inert. Inflation fluid, where a gas, may be, e.g., air, nitrogen, carbon dioxide or other gas. Inflation fluid, where a liquid, may be water, saline, mineral oil, or other liquid. In some embodiment, an inflation fluid may be effective to absorb radiation to, for example, moderate or adjust a dosage of radiation delivered to a patient's tissue from radioactive treatment material 30 contained within a delivery shaft 28.

[0030] Vacuum applied to intermediate space 24 is effective to deliver a treatment within a body cavity 38 within a patient's body effective to urge surrounding tissue into contact with at least a portion of the surface of the outer balloon 14.

[0031] The outer balloon 14 shown in Figs. 1-5 is illustrated as a balloon that is configured to permanently or semi-permanently enclose inner balloon 16 or inner balloon assembly. Such an enclosure may be partial or complete. It will be understood that the outer surface of a device and of a system embodying features of the invention may also be a sheath 50 configured for deployment over and around an inner balloon assembly 14. In further embodiments, an enclosure may be, e.g. a net, mesh, framework, or other discontinuous structure.

[0032] Figure 2 is a longitudinal cross-sectional view of the system of Fig. 1 taken along line 2-2 showing in cross section, for example, the relative positions of treatment material 30, an inner balloon 16, and an outer balloon 14 or sheath 50. Figure 2 includes cross-sectional views of shaft 18 including views of delivery shaft 28, vacuum conduit 34 and inflation conduit 36. Figure 3 is a transverse cross-sectional view of the system of Fig. 1 taken along line 3-3 showing outer balloon 14 and holes 22 therethrough, inner balloon 16 disposed within outer balloon 14, delivery shaft 28 and probe 32.

[0033] Figure 4A and 4B show portions of outer balloon 14 and inner balloon 16 as indicated in Figure 1, including intermediate space 24 and spacers 40 which serve as separation elements effective to maintain patency of intermediate space 24 even under the influence of vacuum supplied via vacuum conduit 34. Spacers 40 may be part of outer balloon 14, or of inner balloon 16, or both. A spacer 40 may be a bump, knob,

ridge, or other feature extending inwardly from an inner surface 42 of outer balloon 14, or extending outwardly from an outer surface 44 of outer balloon 14. In addition, or alternatively, a spacer 40 may be an object that is placed within intermediate space 24 and is separate from outer balloon 14 and inner balloon 16. For example, as shown in Figures 4A and 4B, spacers 40 may be stand-offs extending from an inner surface 42 of outer balloon 14 and from an outer surface 44 of outer balloon 14.

[0034] Figures 5A-5D illustrate the fitting of an outer balloon assembly 46 (including an outer balloon in the form of a sheath 50), over an inner balloon assembly 48 including an inner balloon 16. Figure 5B shows the assembled outer 46 and inner 48 balloon assemblies of Figure 6A following placement into a cavity 38 within a breast 52 of a patient and before inflation of the inner balloon assembly 48. In Figure 5C, the inner balloon assembly 48 has been inflated by passage of inflation fluid through inflation conduit 36, pressing some parts of the outer surface 54 outer balloon assembly 46 into contact with portions of the inner surface 56 of body cavity 38. Note, however, that since most cavities 38 have irregular inner surfaces 56, there will typically be poor and intermittent contact between outer surface 54 of sheath 50 (or outer balloon 14 in alternative embodiments) and inner surface 56 of cavity 38, as shown in Figure 5C.

[0035] Figure 5D shows the assembled outer 46 and inner 48 balloon assemblies of Figure 5A following application of vacuum via vacuum conduit 34 to the intermediate space 24 separating the inner balloon 16 and the sheath 50 (outer balloon 14). Treatment material 30 is in place within delivery shaft 28. Note that inner surface 56 of cavity 38 has been pulled into intimate contact with outer surface 54 of sheath 50. Such intimate contact configures inner surface 56 into an optimal configuration for the

application of treatment by a treatment material 30. For example, radiation treatment by a radiation treatment material 30 is enhanced by proper positioning of adjacent tissue to provide proper irradiation. Irradiation levels may vary widely where the adjacent tissue of tissue cavity 38 is at different, irregular, or improper distances from a radiation source. Application of vacuum effective to draw tissue into better contact with device 12, e.g., into better contact with outer surface 54 of sheath 50, is effective to improve the delivery of radiation treatment from a radioactive treatment material 30.

[0036] Figure 6A illustrates a system embodying features of the invention including a vacuum delivery element comprising an enclosure 60 having ribs 62 configured to partly enclose an inner balloon assembly 48. Vacuum is delivered to intermediate space 24 via vacuum ports 64 operatively connected to vacuum conduit 34. As shown in cross-section in Figure 6B, ribs 62 serve as separation elements effective to provide vacuum paths in the intermediate space 24 between tissue surface 56 and outer surface 44 of inner balloon assembly 48.

[0037] Methods for treating tissue adjacent a body cavity 38 include methods for delivering a treatment to tissue adjacent a device 12 embodying features of the invention. For example, a method of treating tissue adjacent a body cavity 38 includes contacting tissue adjacent the body cavity 38 with a sheath 50 or an outer balloon 14, and applying a vacuum via vacuum conduit 34. The vacuum may be effective to draw adjacent tissue towards and into contact with a sheath 50 or an outer balloon 14, and so enhance the contact between the outer wall 54 and the tissue. Delivery of inflation fluid to an inner balloon 16 via an inflation conduit 36 to inflate inner balloon 16 is effective to enhance contact with adjacent tissue as well, serving to bring outer balloon 14 or sheath

50 closer to tissue than it would be in the absence of inflation of inner balloon 16. In preferred embodiments, the inner balloon assembly 48 comprises an inflatable treatment delivery device such as a Mammosite RTS (Proxima Therapeutics, Inc., Alpharetta, GA 30005) or similar device.

[0038] Methods further include placing a treatment material 30, such as a radiation source, within the device (e.g., by placement within a delivery shaft 28). A radiation source, such as a solid radiation source (e.g., a brachytherapy seeds) may be advanced into a delivery shaft 28 with a probe 32 or by other means. Other solid treatment materials 30 may similarly be advanced into a delivery shaft 28 with a probe 32 or by other means. A liquid radiation source (e.g., Iotrex®, Proxima Therapeutics, Inc., Alpharetta, GA) may be advanced into a delivery shaft 28 by fluid flow, under the influence of gravity, pressure applied by a syringe or other pressure source, or other means for delivering fluid into a space. Similarly, hot liquids and other liquid treatment materials 30 may be introduced into a delivery shaft 28 or an inner balloon 16 (via inflation conduit 36) under the influence of gravity, pressure applied by a syringe or other pressure source, or other means for delivering fluid into a space.

[0039] Some treatment regimens may include periodic or episodic treatment, in which radiation or other treatment is applied for a treatment period, and then the treatment is stopped for a recovery period. Such periodic or episodic treatments may be repeated, so that treatment is applied during a first treatment period, stopped during a first recovery period, and then treatment is re-applied for a second treatment period. Further treatment periods and recovery periods may also be used as necessary. Thus, methods may further include removal of a radiation source or other treatment material

30 from within a delivery shaft 28, and may further include replacing the treatment material 30.

[0040] Although a cavity 38 is typically an artificial cavity remaining after removal of tissue at biopsy, surgery, or other medical procedure, a body cavity may be a natural body cavity. For example, devices 12 may be inserted into a bladder for the treatment of bladder cancer. Application of suction is effective to enhance contact with a device 12 in such an example as well. Such enhanced contact may be effective to improve the delivery of radiation or other treatment, and may be effective to avoid "hot spots" (tissue regions receiving more radiation than is received by neighboring tissue regions) and is one of the important advantages provided by the present invention.

[0041] Treatment material 30 may include a chemotherapy agent effective to treat cancer or other disease condition of tissue surrounding a body cavity 38. In preferred embodiments, treatment material 30 includes a radiation source configured to delivery radiation to tissue adjacent a device 12.

[0042] Thus, treatment material 30 may include a radiation source which may be solid or liquid. A liquid radiation source may include, for example, a liquid containing a radioactive iodine isotope (e.g., ^{125}I or ^{131}I), a slurry of a solid isotope, e.g. ^{198}AU, ^{90}Y, ^{169}Yb, or a gel containing a radioactive isotope. Liquid radiation sources are commercially available (e.g., Iotrex®, Proxima Therapeutics, Inc., Alpharetta, GA).

[0043] A solid radiation source may include brachytherapy seeds or other solid radiation source used in radiation therapy, such as, for example, a radioactive microsphere available from the 3M company of St. Paul, MN. A solid radioactive source can either be preloaded into a device 12 at the time of manufacture or may be loaded

into the device 12 after placement into body cavity 38 of a distal portion of the device 12. Such distal portion preferably includes the outer balloon 14, inner balloon 16, and at least a portion of delivery shaft 28. Such a solid radioactive core configuration offers the advantage in that it allows a wider range of radionuclides than if one is limited to liquids. Solid radionuclides suitable for use with a delivery device embodying features of the present invention are currently generally available as brachytherapy radiation sources (e.g., I-Plant™, Med-Tec, Orange City IA).

[0044] In general, the amount of radiation desired by the physician is a certain minimum amount that is delivered to a site about 0-3 cm away from the wall of the body cavity 38 (e.g., from where a tumor has been excised). Vacuum applied to intermediate space 24 effects good contact between tissue surrounding body cavity 38 and the wall of the outer balloon 14 or sheath 50, promoting effective treatment delivery, such as delivery of radiation to surrounding tissue. It is desirable to keep the radiation in the region near the wall of the outer balloon 14 or sheath 50 as uniform as possible to prevent over-exposure to tissue at or near the reservoir wall. It is well known that the absorbed dose rate at a point exterior to a radioactive source is inversely proportional to the square of the distance between the radiation source and the target point. Thus, it is possible that the radiation dosage delivered to adjacent tissue may differ from that delivered to tissue disposed at more distal locations. In some instances, penetration of radiation to locations far from a device 12 is not desired. For example, in treating cancers such as bladder cancer, where the neoplastic tissue is generally located on the bladder surface, deep penetration is unnecessary and to be avoided.

[0045] An inflation fluid may also be a radiation absorbing fluid. For example, an inflation fluid may be an X-ray contrast agent as used in angiography, such as a Barium salt (e.g., barium sulfate), water, saline or other such fluid. A radiation-absorbing inflation fluid, which will surround a radiation source placed within delivery shaft 28, serves to moderate and control the delivery of radiation from the radiation source to surrounding tissue. Such moderation and control that is obtained with a radiation-absorbing inflation fluid may aid in avoiding the delivery of an excessive amount of radiation to some portions of the surrounding tissue.

[0046] Thus, in the absence of such a radiation-absorbing inflation fluid, it is possible in some instances that a radiation source sufficient to provide an effective dose at distances removed from a device 12, would expose tissue that is directly adjacent the wall of the outer balloon 14 or sheath 50 to an excessive radiation dose. Such excessive exposure to such tissue near to the device 12 may result in necrosis of healthy tissue necrosis.

[0047] Alternatively, an inflation fluid may contain radioactive elements, either as a liquid or slurry, so that the inner balloon 16 is filled with a source of radiation, providing a fairly uniform source of radiation that is distributed over the volume of the inner balloon 16. In such embodiments, an inflation fluid thus itself serves as a radiation source, thereby providing well-controlled amounts of radiation to surrounding tissue while minimizing irregularities in the dosages delivered to particular locations.

[0048] In embodiments of the invention in which an inflation fluid includes a radiation source, a delivery shaft 28 may contain a radiation absorptive material, so that, for example, less volume of radioactive material is required than if the entire volume of a

device 12 were filled with radioactive material. Such a configuration may be advantageous where a profile exhibiting higher intensity at a tissue surface with lesser penetration is desired. Moreover, the outer balloon 14 need not be spherical, yet a uniform profile of radiation delivery is obtainable. Experiments reported in Williams U.S. Pat. No. 5,918,813 are described as showing that a steeper radial absorbed source gradient can be obtained using a radiation attenuation fluid in an inner chamber of a similar radiation deliver device than otherwise obtains with a device having only a single distensible chamber (as described in Williams U.S. Pat. No. 5,429,582).

WHAT IS CLAIMED IS

1. A device for treating tissue adjacent a body cavity, comprising:

an inner balloon assembly including an inflation conduit configured to allow passage of a fluid and an inner balloon comprising a distensible inner balloon wall defining an internal lumen, said inner balloon being operatively connected to said inflation conduit so as to allow for passage of said fluid through said inflation conduit and into said internal lumen effective to inflate said inner balloon with said fluid; and

a sheath assembly comprising a vacuum conduit and a fluid-permeable sheath wall configured to enclose said inner balloon assembly, effective to define an intermediate space between said inner balloon assembly and said sheath assembly, said sheath assembly being operatively connected to said vacuum conduit effective to provide vacuum to said intermediate space.

2. The device for treating tissue adjacent a body cavity of claim 1, wherein said fluid-permeable sheath wall comprises a hole therethrough.

3. The device for treating tissue adjacent a body cavity of claim 1, wherein said fluid-permeable sheath wall comprises a fluid-permeable material.

4. The device for treating tissue adjacent a body cavity of claim 3, wherein said fluid-permeable material comprises a woven material.

5. The device for treating tissue adjacent a body cavity of claim 1, wherein said sheath wall includes separation elements configured to maintain a separation between said sheath wall and said inner balloon wall.

6. The device for treating tissue adjacent a body cavity of claim 1, wherein said inner balloon wall includes separation elements configured to maintain a separation between said sheath wall and said inner balloon wall.

7. The device for treating tissue adjacent a body cavity of claim 1, wherein said sheath wall comprises a flexible material.

8. The device for treating tissue adjacent a body cavity of claim 7, wherein said sheath wall comprises an elastic flexible material.

9. The device for treating tissue adjacent a body cavity of claim 8, wherein said sheath wall comprises an inelastic flexible material.

10. The device for treating tissue adjacent a body cavity of claim 1, wherein said sheath wall comprises a polymer.

11. The device for treating tissue adjacent a body cavity of claim 1, wherein said sheath wall comprises a biocompatible polymer.

12. The device for treating tissue adjacent a body cavity of claim 1, wherein said sheath wall comprises a radiation-resistant polymer.

13. The device for treating tissue adjacent a body cavity of claim 10, wherein said polymer is selected from the group of polymers consisting of a polyolefin, polyethylene, polypropylene, polyurethane, polyester, polyvinylchloride, polystyrene, nylon, latex rubber, silicon rubber, a thermoplastic polymer, C-Flex®, an inonomer, Surlyn®, Kraton™ and SILASTIC™.

14. The device for treating tissue adjacent a body cavity of claim 1, wherein said internal lumen is configured to enclose a treatment material.

15. The device for treating tissue adjacent a body cavity of claim 14, wherein said treatment material is selected from the group consisting of radioactive material, chemotherapeutic agents, and materials having a temperature greater than about 37 °C.

16. The device for treating tissue adjacent a body cavity of claim 1, wherein said sheath assembly comprises an outer balloon assembly and said sheath wall comprises an outer balloon wall.

17. The device for treating tissue adjacent a body cavity of claim 16, wherein said outer balloon wall comprises a polymer.

18. The device for treating tissue adjacent a body cavity of claim 17, wherein said polymer is selected from the group of polymers consisting of a polyolefin, polyethylene, polypropylene, polyurethane, polyester, polyvinylchloride, polystyrene, nylon, latex rubber, silicon rubber, a thermoplastic polymer, C-Flex®, an inonomer, Surlyn®, Kraton™ and SILASTIC™.

19. The device for treating tissue adjacent a body cavity of claim 16, wherein said outer balloon wall is configured to enclose a treatment material.

20. The device for treating tissue adjacent a body cavity of claim 19, wherein said treatment material is selected from the group consisting of radioactive material, chemotherapeutic agents, and materials having a temperature greater than about 37 °C.

21. A system for treating tissue adjacent a body cavity, comprising:

an inner balloon assembly including an inflation conduit configured to allow passage of a fluid and an inner balloon comprising a distensible inner balloon wall defining an internal lumen, said inner balloon being operatively connected to said inflation conduit so as to allow for passage of said fluid through said inflation conduit and into said internal lumen effective to inflate said inner balloon with said fluid; and

a sheath assembly comprising a vacuum conduit and a fluid-permeable sheath wall configured to enclose said inner balloon assembly, effective to define an intermediate space between said inner balloon assembly and said sheath assembly, said sheath assembly being operatively connected to said vacuum conduit effective to provide vacuum to said intermediate space; and

a vacuum source operatively configured to operatively connect with said vacuum conduit.

22. A method for treating tissue adjacent a body cavity, comprising:

contacting tissue adjacent a body cavity with a sheath, said sheath having a fluid-permeable wall with an inner and an outer surface, said sheath being disposed outside of a distensible balloon, said balloon having an inner balloon lumen and containing a treatment material, said inner balloon lumen being operatively connected to an inflation conduit; and

applying a vacuum to said inner surface of said permeable wall of said balloon effective to enhance said contact between said fluid-permeable wall and said tissue.

23. The method for treating tissue adjacent a body cavity of claim 22, further comprising:

delivering inflation fluid to said inner balloon lumen via said inflation conduit effective to inflate said distensible balloon.

24. A method for treating tissue adjacent a body cavity, comprising:

contacting tissue adjacent a body cavity with a balloon assembly, said balloon assembly having a fluid-permeable wall with an inner balloon wall surface and an outer balloon wall surface, said balloon assembly being disposed outside of a distensible inner balloon assembly, said inner balloon assembly having an inner balloon lumen and containing a treatment material, said inner balloon lumen being operatively connected to an inflation conduit; and

applying a vacuum to said inner balloon wall surface of said permeable wall of said balloon effective to enhance said contact between said fluid-permeable wall and said tissue.

25. The method of claim 24, further comprising:

delivering inflation fluid to said inner balloon lumen via said inflation conduit effective to inflate said distensible inner balloon assembly.

26. The method of claim 24, wherein said inner balloon assembly comprises an inflatable treatment delivery device.

27. The method of claim 26, wherein said inflatable treatment assembly comprises a device selected from a MammoSite® RTS, a GliaSite® RTS, and a device similar to a MammoSite® RTS.

28. The method of claim 26, further comprising replacing said treatment material.

29. A method for treating tissue adjacent a body cavity containing a treatment assembly, comprising:

applying a vacuum to said body cavity effective to draw said tissue adjacent the body cavity towards said treatment assembly.

30. The method of claim 29, wherein applying vacuum to said body cavity comprises applying vacuum to said body cavity via a vacuum conduit operatively attached to an enclosure device at least partly enclosing said treatment assembly.

31. A device for enhancing treatment of tissue adjacent a body cavity delivered by a treatment assembly configured for delivering a treatment to tissue adjacent a body cavity, comprising:

enclosure device configured to at least partly enclose a treatment assembly for delivering a treatment to body tissue adjacent a body cavity;

a vacuum conduit; and

a vacuum port operatively connected to said vacuum conduit configured to provide suction adjacent said treatment assembly when said enclosure device is disposed to at least partly enclose said treatment assembly.

32. The device for enhancing treatment of tissue adjacent a body cavity delivered by a treatment assembly configured for delivering a treatment to tissue adjacent a body cavity of claim 31, wherein said treatment assembly comprises an inflatable treatment delivery device.

33. The device for enhancing treatment of tissue adjacent a body cavity of claim 32, further comprising an enclosure assembly configured to at least partially enclose an inflatable treatment delivery device.

34. The device of claim 33, wherein said enclosure assembly comprises a fluid permeable surface.

35. The device of claim 34, wherein said enclosure assembly comprises a sheath.

36. The device of claim 34, wherein said enclosure assembly comprises a balloon.

37. The device of claim 34, wherein said inflatable treatment delivery device comprises a treatment delivery element configured to enclose a treatment material.

38. The device of claim 37, wherein said treatment material comprises a material selected from radioactive material, chemotherapeutic agents, and thermal treatment materials.

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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN JOSE DIVISION

HOLOGIC, INC., CYTYC CORPORATION, and HOLOGIC L.P.,

Plaintiffs,

vs.

SENORX, INC.,

Defendant.

AND RELATED COUNTERCLAIMS.

Case No. C08 00133 RMW (RS)

MANUAL FILING NOTICE

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Judge: Hon. Ronald M. Whyte

Regarding: Exhibits A, D through P, S, and T to the Declaration of Henry C. Su In Support of Plaintiffs' Opposition to Defendant SenoRx, Inc.'s Motion for Partial Summary Judgment of Non-Infringement ('813 Patent, Claims 11 & 12; '204 Patent, Claims 4 & 17; and '142 Patent, Claim 6).

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